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Guidance for the Reregistration of Pesticide Products Containing Dodine as the Active Ingredient

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Pesticides

EPA

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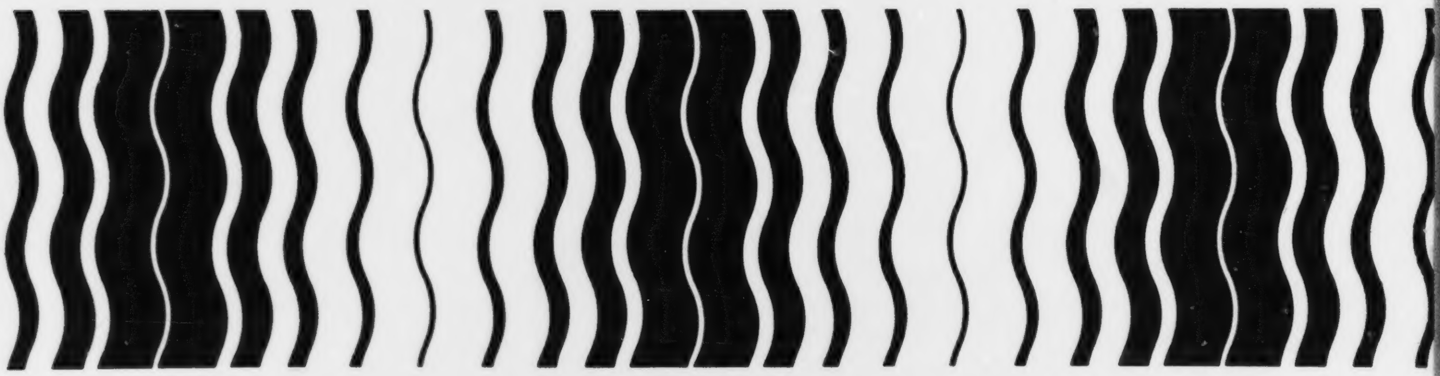

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

Dodecylguanidine acetate
(CAS Number 2439-10-3, OPP Pesticide Chemical Code 044301)

Dodecylguanidine hydrochloride
(CAS Number 13590-97-1, OPP Pesticide Chemical Code 044303)

Dodecylguanidine terephthalate
(CAS Number 19727-17-4, OPP Pesticide Chemical Code 044302)

AS THE ACTIVE INGREDIENT

CASE NUMBER: 0161

FEBRUARY 1987

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

1/ The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of the chemicals

The following chemicals are covered by this Registration Standard:

Chemical Name:	Dodecylguanidine acetate	Dodecylguanidine hydrochloride (DGH)	Dodecylguanidine terephthalate (DGT)
Common Name:	Dodine	None	None
Brand Names:	Doguadine Tsitrex, Dodine acetate, Dodecylguanidine monoacetate, CL 7521, AC 5223, Cyprex, Melprex, Carpene, Curitan, Syllit, Venturol, and Vondodine	Cytox 2013	Durotex 7487-A
CAS Registry Number:	2439-10-3	13590-97-1	19727-17-4
EPA/OPP Pesticide Chemical Code:	044301	044303	044302
Empirical Formula:	$C_{15}H_{33}N_3O_2$	$C_{13}H_{30}N_3Cl$	Not Available

Description of Physical Characteristics of Chemical

Color:	White	Not Available	Not Available
Physical State:	Crystals, Slightly waxy	Not Available	Not Available
Melting Point:	136°C	Not Available	Not Available

Description of Physical Characteristics (Cont'd)

	Dodecylguanidine acetate	Dodecylguanidine hydrochloride (DGH)	Dodecylguanidine terephthalate (DGT)
Solubility:	Soluble at 7-23% in low molecular weight alcohols at room temperature. Soluble in acids and 0.06% soluble in water at 25C. Insoluble in most other solvents. Soluble in ethanol.	Not Available	Not Available
Molecular Weight:	287.4	263.9	Not Available

B. Use Profile

Products containing dodecylguanidine acetate (dodine) were first registered in 1956 for controlling major fungal diseases on fruit and nut crops and on certain ornamental and shade trees. Most of the total volume of dodine is used for treating apple scab. However, dodine resistant apple scab has been found where dodine has been in predominant use for about 10 years. In such cases, it is advantageous for the apple grower to use an unrelated fungicide. In some areas dodine has been used for an extended period without apparent resistance. In these areas it is prudent to use a second fungicide for part of the season to offset the likelihood of the apple scab developing dodine resistance.

Significant volumes of dodine are also used on pears and cherries. As with apple scab, the probability of developing dodine resistant cherry leaf spot can be reduced by incorporating additional fungicides into the pest management program. Other registered agricultural sites for dodine are black walnut, peaches, pecans, and strawberries. Although there is a tolerance for dodine on spinach, there are no products registered for use on this site. Dodine is also registered for the ornamentals: flowering crabapple, sycamore, and rose.

Dodine is also registered for use at several industrial aquatic sites. It is used as a slimicide to control bacteria, fungi, and algae in air washer and cooling tower systems, oil field water systems, and pulp and paper mill systems. In addition to the slimicide uses, dodine is also registered as an industrial preservative for metalworking cutting fluids, oil recovery packer fluids and drilling muds, and paper products.

Dodecylguanidine hydrochloride (DGH) and dodecylguanidine terephthalate are chemically similar to dodine. Although DGH is not registered for agricultural sites, it is registered for the same industrial sites as dodine. DGT is registered as a industrial preservative for non-clothing textiles.

	Dodecylguanidine acetate	Dodecylguanidine hydrochloride (DGH) (DGH)	Dodecylguanidine terephthalate (DGT)
Registered Sites:	Fruit and nut trees, ornamentals, industrial aquatic sites, pulp and paper products	Industrial aquatic sites	Industrial preservative
Predominant Use(s):	Apple trees	Industrial biocide/ preservative	Non-clothing textiles
Formulation Types Registered:	Wettable powder/ dust, soluble concentrate/ liquid	Soluble concentrate/ liquid	Soluble concentrate/ liquid
Method(s) of Application:	Foliar spray, Air blast spray, Dusting equipment drawn by tractor or truck, Boom sprayer, Aerial spray, Automatic pump, Drip Feed, Pour	Automatic pump, Drip Feed, pour	Manual pour, Conventional padding equipment

III. EPA ASSESSMENT

A. INTRODUCTION

EPA reviewed available data supporting registrations of products containing dodine, dodecylguanidine hydrochloride (DGH), and dodecylguanidine terephthalate(DGH). Consequently, EPA has identified additional data needed to evaluate human health and environmental risks associated with the uses of products containing these active ingredients (AI). Registrants must develop these data in order to maintain current product registrations or register new products containing dodine, DGH, or DGT. The following table summarizes the disciplines for which EPA has identified data gaps. In Appendix A, refer to Tables A-1 and B-1 (dodine), A-2 and B-2 (DGH), A-3 and B-3 (DGT) for required studies specific to these AIs.

Note that the toxicological studies evaluated in this standard were all performed on dodine, the acetate salt of dodecylguanidine. Other than for acute effects, dodine and DGH will be considered equivalent because the acetate and hydrochloride anions are expected only to lead to differences in degree of dissociation (i.e., separation into dodecylguanidine and the anions). Also, because the guanidine moiety is common to both salts, and the anions are not expected to behave very differently, no dramatic qualitative or quantitative differences in toxicological properties are expected. Therefore, EPA will consider the subchronic and chronic data submitted for dodine to be applicable to DGH.

Because of the more complex nature of the terephthalate anion, a subchronic oral rodent study will be required for comparison with the current data on dodine to ascertain whether qualitatively or quantitatively different effects result. If the results show significant differences, EPA may require further testing of DGT.

B. SCIENCE FINDINGS

1. Dodine

Product and residue chemistry - Available product chemistry data are limited to some product identity and disclosure of ingredients. There are adequate methods available to determine dodine residues in or on plant commodities. There are adequate data to support the established tolerances for dodine in or on spinach, apples, and pears. Tolerances and residues are further described in Section III. C (Tolerance Reassessment).

Environmental fate - There are no available data allowing EPA to assess the environmental fate of dodine. Similarly, EPA lacks data pertaining to the potential groundwater contamination from dodine use.

Ecological effects - EPA does not have data describing toxicity of technical grade dodine to birds or aquatic organisms. However, data on a formulation containing 95% dodine as well as other active ingredients indicate that dodine is slightly toxic to birds and highly toxic to freshwater fish. A laboratory acute contact study indicates that dodine is relatively nontoxic to honey bees. Based on the incomplete data base, terrestrial dodine food residues pose no apparent acute hazards to any avian or aquatic species that are Federally designated threatened or endangered.

EPA lacks data regarding the acute oral toxicity of technical grade dodine to birds. However, subacute oral studies indicate a dietary LC_{50} greater than 5000 ppm. EPA cannot fully assess subacute toxicity unless data quantifying percent AI is submitted. Although the incomplete data base on technical dodine limits conclusions, available data from studies using end-use products suggest that there would be no immediate hazard to avian species resulting from exposure to terrestial food crop residues. Studies using a typical formulated product found the avian LD_{50} ranged from 700 - 2000 ppm. Estimation of residues to which birds will be exposed are approximately 70 to 170 ppm on leaves and 3-7 ppm on fruit.

EPA calculated the estimated environmental concentration (EEC) in aquatic systems based on assumptions of terrestrial uses of dodine applied at maximum rates to fruit and nut trees with subsequent runoff into a one acre pond. The EEC of 15 ppb is well below the toxic level to fish (650 to 870 ppb). EPA cannot determine hazards to invertebrate species because no data on either technical or formulated products are available. In addition, EPA lacks data quantifying the concentration of dodine in industrial effluents. Therefore, EPA needs monitoring data to estimate the effects of discharge water on aquatic biota.

Toxicology - The available data allow EPA to adequately characterize the acute effects of dodine. The findings of acute oral LD_{50} of 1.46 g/kg, a one hour LC_{50} of 1.05-1.79 mg/l, and no deaths among test animals after acute dermal exposure to 2 g/kg indicate moderate lethal potency (Category III). Severe irritation in both washed and unwashed eyes and severe dermal irritation including erythema and edema were seen in rabbits (Category I). Based on a 21-day skin sensitization study, there is no evidence of sensitization in humans. There are no available studies on acute delayed neurotoxicity; however, based on its structure, dodine would not be expected to exhibit neurotoxic effects.

Although many of the available studies of dodine do not satisfy EPA's data requirements, various effects of dodine can be identified based on existing studies. Subchronic dietary exposure of dogs caused changes in thyroid cells indicative of stimulation (No Observed Effects Level (NOEL) = 1.25 mg/kg). In another study, chronic dietary exposure in the rat caused reduced weight gain in both sexes, accompanied by a comparable reduction in food consumption in males (NOEL = 10 mg/kg). EPA classifies this rat study as supplementary because the histopathology analysis was inadequate.[1] In a study of reproductive effects, dietary exposure of parent mice caused decreases in the number of pups per litter surviving until day 5 and weaning (Lowest Observed Effect Level (LOEL) = 74-89 mg/kg) this is also the lowest dose tested. The results of an Ames assay for mutagenicity of 5 strains of bacteria with and without metabolic activation were negative, i.e. no mutations were observed.

2. DGH

Available product chemistry data are limited to some product identity and disclosure of ingredients. There are no data available describing environmental fate, ecological effects, or toxicology. Data requirements are listed in Table A-2. Note that for some studies, data on dodine will suffice for DGH. In addition, some data requirements are reserved pending results of initial studies to compare the similarity between dodine and DGH.

3. DGT

Available product chemistry data are limited to some product identity and disclosure of ingredients. There are no data available describing environmental fate, ecological effects, or toxicology. Data requirements are listed in Table A-3. Note that some data requirements are reserved pending results of initial studies to determine the similarity between dodine and DGT.

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[1] EPA classifies as supplementary studies that do not fully meet specific regulatory data requirements but nonetheless are considered by EPA to be scientifically sound and contain useful information.

C. TOLERANCE REASSESSMENT

Tolerances have been established for residues of dodine in a variety of raw agricultural commodities, and meat, fat, and meat byproducts (40 CFR 180.172). EPA has evaluated the residue and toxicology data supporting tolerances to make the following regulatory determinations:

°Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA sec. 24(c) and intrastate uses);

°Whether group tolerances can be established in accordance with 40 CFR 180.34(f);

°Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary; and

°Whether the tolerances are expressed accurately and in current terminology.

The regulatory determinations resulting from the EPA's review are in Section IV.A., Regulatory Positions and Rationales.

1. Residue Data.

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in plants, including identification of major metabolites and degradates of dodine. The metabolism of dodine in plants is not well understood. Possible metabolites in apples include creatine and guanidine. Tolerances are expressed in terms of the parent compound, dodine *per se*. Similar studies are not available for animals.

b. Radiolabeled studies on the uptake, translocation and metabolism of dodine in apples. These data are inadequate to determine the uptake of dodine because the studies were not conducted in accordance with label directions. The study did show that limited translocation of dodine from leaves to fruit occurs in apple trees.

c. Analytical methodology for determining the levels of residues of dodine in plants. An adequate Gas-Liquid Chromatography (GLC) method exists for enforcement and analysis of residues. A colorimetric method has been determined to be adequate for data collection, but is not specific enough for enforcement purposes.

d. Data on the levels of residues of dodine in individual raw agricultural commodities. Data are not available to adequately define the nature and levels of residues in animals, feed commodities (currently only apple pomace) or processed foods derived from raw agricultural commodities.

2. Toxicology Data.

EPA calculated a Provisional Acceptable Daily Intake (PADI) based upon the 12 month dog study. The NOEL from this study was 1.25 mg/kg; at higher levels thyroid effects were noted. This dog study is considered only supplementary, and there are significant data gaps for chronic, teratogenic, and oncogenic effects. Therefore, EPA used a uncertainty factor of 1000 (rather than 100) to determine the PADI. Using these numbers, the PADI is 1.25 mg/kg ÷ 1000 or 0.0013 mg/kg. For a 60 kg person, the Maximum Permissible Intake is 0.078 mg/day. The maximum level of dodine residue that may theoretically be available in the diet based on existing tolerances is 0.307 mg/day for a 60 kg person. The percentage of the PADI that has been used for existing tolerances is 0.307 ÷ 0.078 = 393.6%.

Although this result may suggest that persons consuming dodine treated commodities are exposed to potentially harmful levels of dodine, EPA does not believe that these theoretical calculations are representative of actual dietary exposure. Theoretical calculations such as these assume that (1) all permitted crops are treated, (2) such treatments are made to 100% of each crop at the highest permitted dosage rate, and (3) persons consume treated crops containing residues at the maximum level. Each factor in the calculation assumes a worst case exposure situation and thus tends to overestimate the amount of dietary exposure to dodine. For example, EPA's data on production of dodine suggest that it is highly unlikely that 100% of the crops are treated at the maximum application rate.

EPA has no data from actual marketplace sampling by the Food and Drug Administration for dodine residues. However, experience with past sampling of commodities treated with other pesticides indicated that actual residue levels are generally well below the levels to which persons theoretically might be exposed. In addition, the exposure calculation includes spinach, as there is an established tolerance for this crop. However, in practice, there should be no dodine residues on spinach because there are no pesticide products containing dodine that are registered for use on spinach.

3. Tolerances issued.

Tolerances for dodine in raw agricultural commodities are listed in 40 CFR 180.172 and listed below. There are no tolerances or food additive regulations for residues of dodine in animal feeds or processed foods.

Crop	Tolerance (ppm)
Apple	5.000
Cherries	5.000
Meat, including poultry	0.000
Milk and dairy products	0.000
Peaches	5.000
Pears	5.000
Pecans	0.300
Spinach	12.000
Strawberries	5.000
Walnuts	0.300

There are no Mexican tolerances for residues of dodine. Codex MRLs and Canadian tolerances are listed below. Generally, these levels are consistent with U.S. tolerances.

	Codex	Canadian
Apples and pears	5 ppm	5 ppm
Cherries	5 ppm	2 ppm
Peaches	5 ppm	---
Strawberries	5 ppm	5 ppm

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS

EPA bases the following determinations on its review of the available data bases for dodine, DGH, and DGT. These regulatory decisions are subject to revision pending receipt and review of the data by EPA. Details pertaining to scientific findings are in Chapter III of this Registration Standard. Further documentation is reported in the supplementary science chapters for each discipline. Specific data requirements are listed in the appended data tables.

1. Special Review - EPA will not at this time place dodine, DGH, or DGT into Special Review.

Rationale: Based on available data, none of these chemicals meets or exceeds the criteria for conducting a Special Review (40 CFR Part 154.7).

2. Restricted use - EPA will not require restricted use classification for end-use products containing dodine, DGH, or DGT.

Rationale: Dodine is not highly toxic acutely via the inhalation or oral routes. There are data demonstrating that exposure to dodine can cause severe ocular and dermal irritation. However, labeling provisions for protective clothing will minimize acute risks from use of products containing dodine.

3. Protective clothing - EPA has determined that in order to meet the statutory standard for continued registration, labels of products containing dodine, DGH and DGT must bear language requiring the use of either protective clothing or closed mixing - loading systems.

Rationale: Results of acute toxicology studies indicate that dodine causes severe eye and skin irritation. The use of protective clothing, as specified in the labeling section, or closed systems will reduce the potential risk of skin and eye exposure resulting from mixing-loading, application, and early reentry.

4. Endangered species - EPA will not require specific label statements pertaining to the protection of Federally designated threatened or endangered species.

Rationale: The available data for dodine do not suggest that terrestrial food residues pose acute hazards to threatened or endangered species in terrestrial or aquatic systems.

5. Groundwater - EPA is not proposing a label advisory statement regarding groundwater.

Rationale: There are, at present, no data suggesting cause for groundwater concerns.

6. Spinach Tolerance - EPA will revoke, within one year of issuance of this Standard, the spinach tolerance if no use for a pesticide product on spinach is proposed.

Rationale: It is EPA's policy to discontinue residue tolerances on crops for which there are no registered uses.

7. Meat and Milk Tolerances - EPA will revoke or replace the zero tolerances with finite levels in meat and milk. After registrants submit data on dodine residues in apple pomace, EPA will establish any necessary tolerances and delete the restriction against feeding apple pomace to livestock.

Rationale: There should be no tolerances for dodine in meat or milk if residues do not occur in feed items. However, finite tolerances must be established in meat and milk to reflect the probable consumption of feed containing dodine residues. EPA considers the restriction regarding apple pomace to be unenforceable due to the impracticalities inherent in ascertaining that pomace containing dodine, a relatively low-volume fungicide, has been used in livestock feed.

8. Reentry Interval - EPA is not imposing a reentry interval for dodine at this time. However, EPA is requiring a foliar dissipation study and a dermal exposure study to assess hazard to farm workers reentering sites treated with dodine. Protective equipment is also being required for handlers and early reentry workers (see Unit IV for required labeling).

Rationale: Available data indicate that dodine is a severe eye and skin irritant. Some of the registered uses of dodine, i.e., apples, strawberries, and cherries, are prime hand-labor crops which require farmworkers to come into direct contact with the pesticide. EPA is concerned that workers may be exposed to residues of dodine that may cause unreasonable adverse effects. In 1986 EPA received information on one poisoning incident involving a 65% wettable powder solution of dodine mixed with sulfur. In this incident, a crew of approximately 30-40 migrant farmworkers suffered eye and skin irritation and headaches after picking cherries in an orchard that had been sprayed one week earlier with a mixture of dodine and sulfur. At least one worker required hospital emergency room treatment. EPA, therefore, is requiring the following studies to quantitatively determine appropriate reentry provisions: (1) foliar dissipation study to determine if residues of dodine remain on the hand labor crops following application of the pesticide, and (2) dermal exposure study to determine the quantity of dodine to which workers may be exposed after application of the pesticide. Following receipt and review of these data, EPA will develop a regulatory position on reentry as appropriate.

9. Glove Permeability Study - EPA is requiring a glove permeability study for dodine.

Rationale: Glove permeability data will enable EPA to determine appropriate materials which are sufficiently resistant to permeation or breakthrough of formulated products containing dodine to provide reasonable protection to the hands.

10. Aquatic Residues - EPA is requiring aquatic residue monitoring for dodine, DGH and DGT.

Rationale: The use of dodecylguanidine derivatives in cooling towers and industrial processes will lead to discharges into the aquatic environment. There are no models to estimate the amount of dodecylguanidine derivatives to which aquatic species will be exposed. Therefore, a residue monitoring field study must be performed in order to quantify exposure levels.

11. New Uses - EPA will not allow any significant new uses of dodine, DGH, or DGT until data gaps identified in this Standard are filled.

Rationale: The available data are insufficient for EPA to evaluate risks associated with the uses of these chemcials. EPA finds that it is prudent not to permit significantly expanded use of these chemicals until risks can be evaluated.

12. Review of studies - EPA has identified those studies the Agency will review immediately upon receipt of the data. Other data will be reviewed when the Agency schedules a final Registration Standard for dodine.

Rationale: Certain data are critical to EPA's determinations regarding the risks involved with the uses of these chemicals and the possibility that further studies must be initiated. The following studies will receive immediate review.

40 CFR Part 158.125 Residue chemistry

171-4	Nature of metabolism in plants - dodine

40 CFR Part 158.135 Toxicology

82-1	90-day feeding - DGT
82-2	21-day dermal - dodine
83-1	Chronic toxicity, rodent and non-rodent - dodine
83-2	Oncogenicity, 2 species - dodine
83-3	Teratogenicity, 2 species - dodine
83-4	Reproduction, 2 generation - dodine

40 CFR Part 158.145 Ecological effects

72-3	Oyster LC_{50} - dodine, DGH, and DGT
72-7	Aquatic residue monitoring - dodine, DGH, and DGT

40 CFR Part 158.140 Reentry Protection

132-1	Foliar Dissipation
133-3	Dermal Exposure

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain dodecylguanidine acetate, dodecylguanidine hydrochloride, or dodecylguanidine terephthalate as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain dodecylguanidine acetate, dodecylguanidine hydrochloride, or dodecylguanidine terephthalate as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing dodecylguanidine acetate, dodecylguanidine hydrochloride, or dodecylguanidine terephthalate provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products registered for uses listed in Appendix III, EPA Index to Pesticide Chemicals. This index lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All manufacturing-use and end-use products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing dodecylguanidine acetate, dodecylguanidine hydrochloride, or dodecylguanidine terephthalate may be released for shipment by the registrant after 28 February 1988, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing dodecylguanidine acetate, dodecylguanidine hydrochloride, or dodecylguanidine terephthalate may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after 28 February 1989 unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement for MPs must list the active ingredient as: dodine, dodecylguanidine hydrochloride, or dodecylguanidine terephthalate.

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Appendix III, Use Index. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

a. Unless the product bears labeling requiring the use of a closed mixing-loading system, a personal protective equipment statement must appear on the label for Manufacturing Use products and End Use products. The statement must read for manufacturing-use products:

PERSONAL PROTECTIVE EQUIPMENT

Pesticide Handlers: During mixing/loading or formulating of the concentrate, wear a long-sleeved shirt, long-legged pants (or coveralls), chemical-resistant apron, chemical resistant gloves, chemical-resistant shoes, shoe covers, or boots, and goggles or face shield.

b. The statement must read for agricultural uses - aerial and ground (airblast) applications - fruit fungicide (liquid, dust, and other formulations applied as sprays):

PERSONAL PROTECTIVE EQUIPMENT

Pesticide Handlers: During mixing/loading of the concentrate, wear a long-sleeved shirt, long-legged pants (or coveralls), chemical-resistant gloves, chemical-resistant shoes, shoe covers, or boots, chemical-resistant apron, and goggles or face shield. During application of the product, wear the same protective clothing, except that a chemical-resistant hat with a wide brim must be worn and the chemical-resistant apron need not be worn. The applicator using an enclosed tractor cab with positive pressure filtration or an enclosed cockpit must wear long pants or coveralls, long-sleeved shirt, socks and shoes. During aerial application in a non-enclosed cockpit, a helmet with a visor may be substituted for the hat and goggles; chemical-resistant shoes, shoe coverings, or boots may be omitted.

c. The statement must read for dust formulations - agricultural uses:

PERSONAL PROTECTIVE EQUIPMENT

Pesticide Handlers: Mixer/loader/applicators must wear long-sleeve shirt, long-legged pants (or coveralls), socks, shoes, chemical-resistant gloves plus any existing label-required protection.

d. For early re-entry for all agricultural end-use products the statement should read:

EARLY REENTRY

Do not enter or allow entry into treated areas until[sprays have dried/dusts have settled/vapors have dispersed, as applicable] to perform hand labor tasks. Workers must wear a long-sleeved shirt, long-legged pants (or coveralls), chemical-resistant gloves, socks, and shoes for early reentry into treated areas to perform other tasks before [sprays have dried, dusts have settled, or vapors have dispersed].

e. For industrial products all product (end-use) labels must require chemical resistant gloves and face shield (or goggles) when handling product.

f. All end-use products must have the following statement about decontamination:

Wash thoroughly with soap and water after handling and before eating, toileting, or smoking.

Remove and wash clothing before reuse. Launder clothing separately from household articles. Replace gloves frequently. Any clothing which has been drenched or heavily contaminated and used gloves must be disposed of in accordance with state or local regulations.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling, or packaging of the product. The applicable requirements depend on whether the product is a manufacturing use or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing dodine, DGH, or DGT as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B 1/.

1/ Data requirements are listed in the Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables. Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption, the data requirements listed in Table C.[2],[3]

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[2] Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore, most Registration Standards do not contain a Table C.

[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B). Two circumstances nullify this exemption: (1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A. (2) If no product subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the data requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.4/

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

4/ Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting required data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing data requirements;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances.

If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing [name of pesticide] as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing [name of pesticide] as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing [name of pesticide] either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

John Lee, Product Manager 31
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Table A contains generic data requirements that apply to the specified AI in all products. This includes data requirements for which the test substance is a "typical formulation". Table B present product-specific data requirements that apply only to a manufacturing use product. The data tables are generally organized according to the format outlined below.

1. Data Requirement (Column 1). The data requirements are listed in the order of apperance in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines. The Guidelines are available from the National Technical Information (NTIS), 5285 Port Royal Road, Springfield, VA 22161. Attn: Order Desk, Phone 703-487-4650.

2. Test Substance (Column 2). This column lists the composition of the required test substance as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, EPA may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, EPA may determined that the data are acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If EPA has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that EPA has only partial data or no data, this column will usually indicate YES. In some cases, even though EPA does not have the data, EPA will not require its submission because of the unique characteristics of the chemical, data on another chemical can be used to fulfill the data requirement, or the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, then column 7 indicates when the data are to be submitted. The time allowed is calculated based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	Yes	Desk references[1]	No	
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	Partially	00101353 00101403 00143591	Yes[2]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	Partially	00143591	Yes[3]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No		Yes[4]	12 Months
62-2 - Certification of Limits	TGAI	All	No		Yes[5]	12 Months
62-3 - Analytical Methods	TGAI	All	Partially	00143591	Yes[6]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No		Yes	6 Months
63-3 - Physical State	TGAI	All	No		Yes	6 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-4 - Odor	TGAI	All	No		Yes	6 Month
63-5 - Melting Point	TGAI	All	No		Yes	6 Month
63-6 - Boiling Point	TGAI	All	No		Yes	6 Month
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No		Yes	6 Month
63-8 - Solubility	TGAI or PAI	All	Partially	00101362	Yes	6 Month
63-9 - Vapor Pressure	PAI	All	No		Yes	6 Month
63-10 - Dissociation constant	PAI	All	No		Yes	6 Month
63-11 - Octanol/water partition coefficient	PAI	All	No		Yes	6 Month
63-12 - pH	TGAI	All	No		Yes	6 Month
63-13 - Storage Stability	TGAI	All	No		Yes	6 Month
Other Requirements:						
64- 1 - Submittal of samples	TGAI	All	No		No	

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

1/ Information obtained from the following desk references: Acceptable Common Names and Chemicals Names for the Ingredient Statement on Pesticide Labels 4th Ed., 1979, p. 113 U.S. EPA, EPA-540/9-77-017; Farm Chemicals Handbook, 1986, p. C 91 Meister Publishing Co., Willoughby, Ohio; Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, Marshall Sittig (Ed.), Noyes Data Corp. p. 354; The Pesticide Manual: A World Compendium, 7th ed., Worthing and Walker (Eds.), British Crop Protection Council, 1983, p. 229.

2/ The registrant must submit details of a manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

3/ The registrant must provide a discussion of each impurity, including any N-nitroso compounds, believed to be present at $\geq 0.1\%$ (≥ 1 ppm in the case of nitrosamines) based on knowledge of the beginning materials, all possible chemical reactions and any contamination.

4/ Registrants must analyze 5 or more representative samples for the amount of AI and each impurity or intentionally added inert ingredient present for which a certified limit is required (greater than 0.1%). Validated analytical methods must be used.

5/ Upper and lower limits for dodine and for each intentionally added inert ingredient, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified. In the case of nitrosamines, two samples of each product must be analyzed shortly after production, 3 months after production, and 6 months after production. Validated methods (sensitive to 1.0 ppm in the case of N-nitroso compounds) must be used. An upper limit must be provided and certified for all N-nitroso compounds found.

6/ The registrant must submit quantitative methods to determine dodine (confirmatory). The method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-4 - Nature of Residue (metabolism)					
o Plant	PAIRA	Partially	00058170	Yes 1/	24 Months
o Livestock	PAIRA and Plant Metabolites	No		Reserved 2/	12 Months
171-4 - Residue Analytical Method					
Plant residues	TGAI and Metabolites	Partially	00034562 - 00090258 00089415 - 00101357 00094615 - 00101385 00101358 - 00101371 00101393 -	Yes 3/	18 Months
Animal Residues	TGAI and Metabolites	No		Reserved 4/	
171-4 - Storage Stability	PAI	No		Yes 5/	24 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
171-4 Magnitude of the residue in plants					
Leafy vegetables group[6]					
Spinach[7]	TEP	Yes	00101371 - 00101373	No	
Pome fruits group[8]					
Apples	TEP	Partially	00096154 - 00035127 00089415	Yes[9]	12 Months
Pears	TEP	Yes	00034562	No[10]	
Stone fruits groups[11]					
Cherries, sweet and sour	TEP	Partially	00089417 - 00101357	Yes[12]	24 Months
Peaches	TEP	Partially	00090258 - 00093588 00101357	Yes[13]	24 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
Small fruits and berries group[14/]					
Strawberries	TEP	Partially	00089881	Yes[15/]	24 Months
Tree nuts[16/]					
Pecans	TEP	Partially	00101358	Yes[17/]	24 Months
Walnuts	TEP	No		No[18/]	
171-4 Magnitude of residues in meat, milk, and poultry	TGAI or plant metabolites	No		Reserved[19/]	18 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

§158.125 Residue Chemistry - Footnotes

1/ Registrants must submit data depicting the uptake, distribution, and metabolism of [^{14}C] dodine (radiolabeled on the guanidine carbon) in apples and strawberries following foliar applications. The test compound must be applied directly to developing fruit. Residues in mature plant parts must be identified and quantified. Application rates must be sufficiently high to permit characterization of all of the radiolabeled residues. Identification of all residues must be confirmed by analytical methods such as gas liquid chromatogaphy (GLC), high pressure liquid chromatography (HPLC), and/or mass spectrometry. The solvent extraction efficiency of dodine residues from mature plants must be determined. If the efficiency is low, further extraction using hydrolysis techniques may be needed to release bound or conjugated residues. Representative samples must be analyzed by enforcement methods to ascertain that all metabolites and impurities of concern are determined by these methods.

2/ If residues of concern are found in apple pomace, registrants must submit metabolism studies utilizing ruminants and poultry. Animals must be dosed for at least three days with guanidine-labeled [^{14}C] dodine at a concentration in the total diet that will result in sufficient residues for characterization in muscle, fat, kidney, liver, and milk. Animals must be sacrificed within 24 hours of the final dosing. Milk must be collected twice daily. Data depicting residue levels in eggs will not be required, since apple pomace is not fed to laying hens. Representative samples must be analyzed by enforcement methods to ascertain that all metabolites and impurities of concern are determined by these methods.

3/ Residues of dodine per se in or on crop samples must be analyzed by the multiresidue methods published as an addendum to subdivision D of the Guidelines. Protocols for methods I, II, III, and IV are available from National Technical Information Service (NTIS) Order No. PB 86 203734/AS.

4/ Residue analytical methods in animals are not presently required. However, if residues of concern are detected in the animal metabolism studies, EPA may require analytical methods for dodine residues in animal products.

5/ Registrants must submit information on the intervals and conditions under which samples were stored to support all established tolerances for residues of dodine; similar information must accompnay any new data generated in response to this standard. These data must be accompanied by data depicting the percent decline in residues at the time and under the conditions specified. On receipt of these data, EPA will reevaluate the adequacy of the tolerances. These data must be accompanied by fortification recovery data depicting the stability of dodine residue of concern in appropriate sample substrates under the conditions and for the time intervals specified. It should be noted that the nature of the residue in plants and animals has not been adequately described. Therefore, if the requested plant metabolism data reveal additional metabolites of toxicological concern, EPA will require data reflecting the storage stability of those metabolites. Also, if residues of concern transfer to animal commodities, EPA will require data depicting the stability of the residues of concern in animal product.

6/ If a crop group tolerance is desired, registrants should propose use directions and submit appropiate supporting residue data for the additional representative group members head lettuce, leaf lettuce, and celery.

7/ The submitted data adequately support the established tolerance under the proposed use directions and limitations. No additional data will be required if any party proposes to register dodine for spinach. If a use is not approved within a year of issuance of this Standard, the tolerance will be revoked.

8/ If a crop group tolerance is desired, registrants should submit data depicting dodine residues of concern in or on pears after multiple foliar applications at 5-day intervals (as needed) throughout the growing season as follows: (i) wettable powder applied aerially at 1.95 lb AI/acre or 0.49 lb AI/100 gal of spray suspension with the last application made seven days before harvest (in OR tests must also include ULV applications in 5-7 gal/acre); (ii) of a dust at 1.6 lb AI/acre with the last application made five days before harvest; and (iii) of a dust at 2 lb AI/acre with the last application made seven days before harvest. Registrants should submit separate tests for dusts using aerial and ground equipment. Registrants should propose a maximum seasonal foliar application rate or a maximum number of foliar applications per season. Required studies must reflect these use limitations. Registrants should conduct tests in CA, OR, and NY. These states collectively account for about 68% of U.S. pear production and are representative of all the major U.S. production regions (Agricultural Statistics, 1985, p. 214).

9/ The available data adequately support the established tolerance for residues of dodine in or an apples. However, EPA no longer considers the restriction against using dodine-treated apples for the manufacture of the livestock feed apple pomace to be practical or enforceable. Therefore, registrants must submit data depicting dodine residues of concern in wet and dry pomace and juice processed from apples bearing measurable, weathered residues. Appropriate food/feed additive tolerances must be proposed if concentration of residues occurs in processed products.

10/ The available data are insufficient to assess the adequacy of the established dodine residue tolerance in or on pears. However, EPA will not require additional data because data translated from apples adequately support the established tolerance for pears.

11/ If registrants seek a crop group tolerance they must submit additional data to support the established tolerance(s) for residues of dodine in or on the representative group members cherries and peaches. Refer to the appropriate crop sections for details of data requirements. Registrants must propose use directions and submit appropriate supporting residue data for the additional representative group member plum/fresh prunes.

12/ Registrants must submit data depicting dodine residues of concern in or on sweet and sour cherries on the same day following the last of several foliar applications (at 7 day intervals) of the 65% wettable powder applied with aerial equipment at 1.3 lb AI/acre. Registrants must submit separate tests for dust formulations applied with aerial and ground equipment at 2.4 lb AI/acre. Registrants must propose a maximum seasonal applicatin rate or maximum number of applications per season and the required studies must reflect these proposals. Tests must be conducted in CA, MI, and WA for sweet cherries, and MI and PA for sour cherries. These states represent approximately 75% and 80%, of 1984 sweet and sour cherry producing areas, respectively (Agricultural Statistics, 1985, p. 194).

13/ Registrants must submit data depicting dodine residues of concern in or on peaches following multiple foliar applications (by ground and, in separate tests, aerial equipment) of a 65% wettable powder formulation at 0.325 lb AI/100 gal or 1.3 lb AI/acre. Foliar applications should begin at shuck split or, in western states, when petals begin to open, and continued at 7-day intervals until 15 days prior to harvest. Tests must be conducted in CA, GA, OR, and SC which collectively produce about 80% of the U.S. peach crop (Agricultural Statistics 1985, p. 211). The registrant must propose a maximum seasonal application rate or a maximum number of applications per season and the required studies must reflect this number.

14/ If a crop group tolerance is desired, registrants should submit additional data to support the established tolerance for residues of dodine in or on the representative group member strawberries. Refer to the strawberry section for details of data requirements. Registrants should propose use directions and submit appropriate supporting residue data for additional representative group members blueberries, blackberries, cranberries, and grapes.

15/ Registrants must submit data depicting dodine residues of concern in or on strawberries harvested 14 days following multiple foliar applications (at 7-day intervals) of a dust or wettable powder formulation at 1.3 lb AI/acre Registrants must conduct separate tests using ground and aerial equipment to apply a dust and using aerial equipment to apply a wettable powder. Registrants must propose a maximum permissible number of applications per season or a maximum lb AI/acre/season rate. The required tests must reflect the maximum seasonal rate proposed. Tests should be conducted in CA, FL, and NY, states which collectively represent about 93% of 1984 U.S. strawberry productng areas (Agricultural Statistics, 1985, p. 221).

16/ If a crop group tolerance is desired, registrants should submit additional data to support the established tolerance for residue of dodine in or on the representative group member, pecans. Refer to the pecans section for details of data requirements. In addition, registrants should submit data depicting dodine residue of concern in or on walnuts sampled following multiple foliar applications of the 65% wettable powder at 0.65 lb AI/100 gal or 2.6 lb AI/acre applied at 10-day intervals by ground and aerial equipment, respectively in separate tests. Tests must be conducted in CA which accounts for about 99% of U.S. English walnut production (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, p. 368). The registrant must propose a PHI and a maximum seasonal foliar application rate or maximum number of foliar applications per season. The required studies must reflect these proposals. Use limitations proposed must be similar to pecans in order for a crop group tolerance to be considered. Registrants should propose use directions and submit appropriate supporting residue data for one additonal representative group member, almonds.

17/ Registrants must submit data depicting dodine residues of concern in or on pecan nutmeats sampled following multiple foliar applications of the 65% wettable powder (through shuck-split) at 4.55 lb AI/acre or 0.65 lb AI/100 gal and 2.6 lb AI/acre or 0.13 lb AI/100 gal applied at 10-day intervals by ground and aerial equipment, respectively, in separate tests. Registrants must conduct tests in GA, NM, and TX, states which represent about 73% of 1984 U.S. pecan production areas (Agricultural Statistics, 1985, p. 234). Registrants must propose a PHI and a maximum seasonal foliar application rate or maximum number of foliar application per season. The required studies must reflect these proposals.

18/ EPA does not have data to evaluate the established tolerance for dodine residues in or on walnuts. However, EPA will not require data because the data requested for pecans can be translated to walnuts.

19/ The nature of the residue in animals and animal products (including meats, milk, and poultry) is not adequately understood. Currently there are no tolerances for residues of dodine in animal products. If residues of concern are found in apple pomace, EPA will require livestock metabolism studies. On receipt of the data requested in the section entitled "Nature of Residue in Livestock (Metabolism)," EPA will determine the necessity for livestock (ruminant and poultry) feeding studies and, if appropriate, determine the adequacy of any proposals for tolerances for residues in animal products.

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,D	No	00131135	Yes	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,D	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	N/A	No		No 1/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes 2/	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A,D	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,D	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Yes	12 Months
163-3 - Volatility (Field)	TEP		No		Reserved 3/	

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	D	No		Yes	27 Months
164-3 - Forestry	TEP	1/	No		No 1/	
164-4 - Combination and Tank Mixes		4/			No 1/	
164-5 - Soil, Long-term	TEP		No		Reserved 5/	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	1/	No		No 1/	
165-2 - Rotational Crops (Field)	TEP	1/	No		No 1/	
165-3 - Irrigated Crops	TEP	A,D	No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,D	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	D	No		Yes	12 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

§158.130 Environmental Fate - Continued

1/ Not required for this AI due to the nature of the use patterns.

2/ Anaerobic aquatic metabolism may be substituted for these data.

3/ Reserved, depending on results of laboratory volatility tests.

4/ This RS for single AI pesticides only.

5/ Reserved, depending on results of field dissipation studies (164-1).

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Oral LD_{50} - Rat	TGAI		Yes	00124280	No	
81-2 - Dermal LD_{50}	TGAI		Yes	00124280	No	
81-3 - Inhalation LC_{50} - Rat	TGAI		Yes	00070339	No	
81-4 - Eye Irritation - Rabbit	TGAI		Yes	00124280	No	
81-5 - Dermal Irritation - Rabbit	TGAI		Yes	00124280	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI		Yes	00157386	No	
81-7 - Delayed Neurotoxicity - Hen	TGAI		No		No 1/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent	TGAI		Yes	00082517	No 2/	
- Non-rodent	TGAI		No		No 2/	
82-2 - 21-Day Dermal	TGAI		No		Yes	12 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
82-3 - 90-Day Dermal	TGAI		No		No 3/	
82-4 - 90-Day Inhalation - Rat	TGAI		No		No 4/	
82-5 - 90-Day Neurotoxicity Hen/Mammal	TGAI		No		No 1/	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:						
- Rodent, and	TGAI		No		Yes	50 Months
- Non-rodent	TGAI		No		Yes	50 Months
83-2 - Oncogenicity - 2 species:						
- Rat (preferred), and	TGAI		No		Yes	50 Months
- Mouse (preferred)	TGAI		No		Yes	50 Months
83-3 - Teratogenicity - 2 species	TGAI		No		Yes	15 Months
83-4 - Reproduction 2-generation	TGAI		No		Yes	30 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI		Yes	00101372	No	
84-2 - Chromosomal Aberration	TGAI		No		Yes	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI		No		Yes	12 Months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA		No		Yes	24 Months

1/ Dodine, by virtue of its structure or known toxicity, does not require a delayed neurotoxicity study.

2/ Since chronic studies in a rodent and non-rodent species are required, 90-day feeding studies are not required. Subchronic level studies are necessary to set dosage levels for these chronic studies, but need not be submitted to the Agency.

3/ Uses do not involve purposeful prolonged, or comparable dermal exposure.

4/ Repeated inhalation exposure at toxic concentrations is not expected.

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No		yes	27 Months
133-3 - Dermal Exposure	TEP	A	No		yes	27 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI TEP	A,D A	No Partially	 101397 1/	Yes No	9 Months
71-2 - Avian Dietary LC_{50}	TGAI	A,D	Partially	106142 2/	Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A	No		No	
71-4 - Avian Reproduction	TGAI	A	No		Yes 3/	24 Months
71-5 - Simulated and Actual Field Testing Mammals and Birds	TEP	A	No		No	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}	TGAI	A,D	No		Yes	9 Months
	TEP 5/	D 4/	Yes	101394 101395	No	
72-2 - Freshwater Invertebrates LC_{50}	TGAI	A,D	No		Yes	9 Months
	TEP 5/	D 4/	No		Yes	9 Months

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-3 - Estuarine and Marine Organism LC_{50}						
- Fish	TGAI	D	No		Yes	12 Months
	TEP 5/	D	No		Yes	12 Months
- Shrimp	TGAI	D	No		Yes	12 Months
	TEP 5/	D	No		Yes	12 Months
- Oyster	TGAI	D	No		Yes	12 Months
	TEP 5/	D	No		Yes	12 Months
72-4 - Fish Early Life Stage, and Invertebrate Life Cycle						
- Freshwater	TGAI	D	No		Reserved 6/	
- Estuarine	TGAI	D	No		Reserved 6/	
72-5 - Fish Life Cycle	TGAI	D	No		Reserved 7/	
72-6 - Aquatic Organism Accumulation	TEP	D	No		No	

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	D	No		Yes 8/	3 Months (Protocol) 24 Months

1/ Study would be acceptable if age of birds were reported to be 16 weeks. However, no requirement exists for presently registered uses.

2/ Study may fulfill requirement if percent AI is reported.

3/ Test required because dodine can be applied multiple times during or before breeding season.

4/ Required to support uses in paper and pulp mills, cooling towers, and oil water systems.

5/ A typical end-use product would contain 10% of a dodecylguanidine compound.

6/ EPA may require both fish and invertebrate studies to support paper and pulp mill, cooling tower, and oil water system uses based on the results of the aquatic monitoring study.

7/ Reserved pending results of fish early life stage and invertebrate life cycle tests.

8/ Registrants must monitor dodine in industrial effluents and receiving waters where it is used in cooling towers, pulp and paper mills, and oil operations and where there is a likelihood of effluent discharge to aquatic ecosystems. Based on relevant factors (i.e. geographic sites, amount AI used, etc.) registrants must develop acceptable protocols within 3 months to sample a representative number of the above facilities. EPA is requiring this data to assess effects of dodine to endangered aquatic species and chronic effects to aquatic biota. Registrants must consider the following when developing protocol: (i) the samples should be analyzed for dodine, (ii) use of standard methods (HPLC or mass spectraphotometry/gas chromatography(MSGC)) to measure dodine, (iii) sites selected for sampling should be where dodine is currently being used and be representative of small and large facilities and/or volumes, (iv) sites selected must also be presentative of a range in volume of the receiving waters and freshwater and estuarine systems; (v) samples from receiving water should be taken before and after treatment, (vi) sampling should be performed at regular intervals for a long enough period to account for such things as seasonal and use variations.

TABLE A-1
GENERIC DATA REQUIREMENTS FOR DODINE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact LC_{50}	TGAI	A,B	Yes	00036935	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No		No 1/	
141-4 - Honey bee subacute feeding study	Reserved2/					
141-5 - Field testing for pollinators	TEP	A,B	No		No 1/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	Reserved3/					
142-2 - Aquatic insect life-cycle study	Reserved3/					
142-3 - Simulated or actual field testing for aquatic insects	Reserved3/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	Reserved3/					

1/ As data from the acute contact study indicate low toxicity, no further testing is required.
2/ Reserved pending development of test methodology.
3/ Reserved pending EPA decision as to whether the data requirement should be established.

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	Partially	Desk reference[1]	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	Partially		Yes[2]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No		Yes[3]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No		Yes[4]	12 Months
62-2 - Certification of Limits	TGAI	All	No		Yes[5]	12 Months
62-3 - Analytical Methods	TGAI	All	No		Yes[6]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No		Yes	6 Months
63-3 - Physical State	TGAI	All	No		Yes	6 Months

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-4 - Odor	TGAI	All	No		Yes	6 Month
63-5 - Melting Point	TGAI	All	No		Yes	6 Month
63-6 - Boiling Point	TGAI	All	No		Yes	6 Month
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No		Yes	6 Month
63-8 - Solubility	TGAI or PAI	All	No		Yes	6 Month
63-9 - Vapor Pressure	PAI	All	No		Yes	6 Month
63-10 - Dissociation constant	PAI	All	No		Yes	6 Month
63-11 - Octanol/water partition coefficient	PAI	All	No		Yes	6 Month
63-12 - pH	TGAI	All	No		Yes	6 Month
63-13 - Storage Stability	TGAI	All	No		Yes	6 Month
Other Requirements:						
64- 1 - Submittal of samples	TGAI	All	No		No	

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

1/ Information obtained from the following desk references: Acceptable Common Names and Chemicals Names for the Ingredient Statement on Pesticide Labels 4th Ed., 1979, p. 113 U.S. EPA, EPA-540/9-77-017; Farm Chemicals Handbook, 1986, p. C 91 Meister Publishing Co., Willoughby, Ohio; Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, Marshall Sittig (Ed.), Noyes Data Corp. p. 354; The Pesticide Manual: A World Compendium, 7th ed., Worthing and Walker (Eds.), British Crop Protection Council, 1983, p. 229.

2/ The registrant must submit details of a manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process purification procedures and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

3/ The registrant must provide a discussion of each impurity, including any N-nitroso compounds, believed to be present at ≥ 0.1% (≥ 1 ppm in the case of nitrosamines) based on knowledge of the beginning materials, all possible chemical reactions and any contamination.

4/ Registrants must analyze 5 or more representative samples for the amount of AI and each impurity or intentionally added inert ingredient present for which a certified limit is required (greater than 0.1%). Validated analytical methods must be used.

5/ Upper and lower limits for dodine and for each intentionally added inert ingredient, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified. In the case of nitrosamines, two samples of each product must be analyzed shortly after production, 3 months after production, and 6 months after production. Validated methods (sensitive to 1.0 ppm in the case of N-nitroso compounds) must be used. An upper limit must be provided and certified for all N-nitroso compounds found.

6/ The registrant must submit quantitative methods to determine dodine (confirmatory). The method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE A - 2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibiographic Citation	Must Additional Data Be Submitted	Time Frame For Submission
§ 158.130 Envionmental Fate						
DISSIPATION STUDIES LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	D			Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	D	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	1/	No		No	
161-4 - In Air	TGAI or PAIRA	1/	No		No	
METABOLISM STUDIES LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	1/	No		No	
162-2 - Anaerobic Soil	TGAI or PAIRA	1/	No		No 2/	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		Yes	12 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	D	No		No	
163-2 - Volatility (LAB)	TEP	1/	No		No	
163-3 - Volatility (Field)	TEP	1/	No		No	

TABLE A - 2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibiographic Citation	Must Additional Data Be Submitted	Time Frame For Submission
§ 158.130 Envionmental Fate - Continued						
DISSIPATION STUDIES FIELD:						
165-1 - Soil	TEP	1/	No		No	
164-2 - Aquatic (Sediment)	TEP	D	No		Yes	27 Months
164-3 - Forestry	TEP	1 /			No 1/	
164-4 - Combination and Tank Mixes		3/	No		No 3/	
165-5 - Soil, Long-term	TEP	1/	No		No	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	1/	No		No 1/	
165-2 - Rotational Crops (Field)	TEP	1/	No		No 1/	
165-3 - Irrigated Crops	TEP	D	No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	D	No		Yes	12 Months
165-5 - In Aquatic nontarget Organisms	TEP	D	No		Yes	12 Months

Table A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

§158.130 Environmental Fate - Footnotes

1/ Not required for this AI due to the nature of the use patterns.

2/ Anaerobic aquatic metabolism may be substituted for these data.

3/ This RS for single AI pesticides only.

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Oral LD_{50} - Rat	TGAI		No		Yes	9 Months
81-2 - Dermal LD_{50}	TGAI		No		Yes	9 Months
81-3 - Inhalation LC_{50} - Rat	TGAI		No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI		No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI		No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI		No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI		No		No 4/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI		Yes	00082517	No 1/	
- Non-rodent	TGAI		No		Yes 1/	18 Months

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
82-2 - 21-Day Dermal	TGAI		No		Yes[1]	12 Months
82-3 - 90-Day Dermal	TGAI		No		No[2]	
82-4 - 90-Day Inhalation - Rat	TGAI		No		No[3]	
82-5 - 90-Day Neurotoxicity Hen/Mammal	TGAI		No		No[4]	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species						
- Rodent	TGAI		No		Yes[1]	50 Months
- Non-rodent	TGAI		No		Yes[1]	50 Months
83-2 - Oncogenicity - 2 species						
- Rat (preferred)	TGAI		No		Yes[1]	50 Months
- Mouse (preferred)	TGAI		No		Yes[1]	50 Months
83-3 - Teratogenicity - 2 species	TGAI		No		Yes[1]	15 Months
83-4 - Reproduction 2-generation	TGAI		No		Yes[1]	39 Months

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI		Yes	00101372	No	
84-2 - Chromosomal Aberration	TGAI		No		Yes[1]	12 months
84-4 - Other Mechanisms of Mutagenicity	TGAI		No		Yes[1]	12 months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA		No		Yes[1]	24 months

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[1] EPA will consider data on dodine as equivalent for dodecylguanidine hydrochloride.

[2] Uses do not involve purposeful, prolonged, or comparable dermal exposure.

[3] Repeated inhalation exposure at toxic concentrations are not expected.

[4] Dodecylguanidine hydrochloride, by virtue of its structure or known toxicity, does not require a delayed neurotoxicity study.

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	D	No		No 1/	
71-2 - Avian Dietary LC_{50}	TGAI	D	No		Yes 1/	9 Months
71-3 - Wild Mammal Toxicity	TGAI	D	No		No	
71-4 - Avian Reproduction	TGAI	D	No		No	
71-5 - Simulated and Actual Field Testing Mammals and Birds	TEP	D	No		No	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}	TGAI	D	No		Yes2/	9 Months
	TEP4/	D 3/	No		Yes	9 Months
72-2 - Freshwater Invertebrates LC_{50}	TGAI	D	No		Yes	9 Months
	TEP4/	D3/	No		Yes	9 Months

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-3 Estuarine and Marine Organisms LC_{50}						
- Fish	TGAI	D	No		Reserved5/	
	TEP5/	D3/	No		Reserved5/	
- Shrimp	TGAI	D	No		Reserved5/	
	TEP5/	D3/	No		Reserved5/	
- Oyster	TGAI	D	No		Yes	12 Months
	TEP4/	D3/	No		Yes	12 Months
72-4 - Fish Early Life Stage, and Invertebrate Life Cycle						
- Freshwater	TGAI	D	No		Reserved6/	
- Estuarine	TGAI	D	No		Reserved6/	
72-5 - Fish - Life-Cycle	TGAI	D	No		Reserved7/	
72-6 - Aquatic Organism Accumulation	TEP	D	No		No	

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	D	No		Yes 8/	24 Months (protocol- 3 months)

1/ For an aquatic nonfood use, only a single dietary study, preferably on the mallard duck, is required.

2/ A single fish species is required. If the results indicate that DGH toxicity is significantly different from dodine, the second species may be required.

3/ Required to support uses in paper and pulp mills, cooling towers, and oil water systems.

4/ The typical end-use product used should contain 10% DGH. Toxicity data using end products containing 10% dodine may be substituted.

5/ Studies on dodine will suffice unless the results of the oyster larvae study on DGH are an order of magnitude different from the same study using dodine. The oyster larvae study will serve as the comparitive estuarine organism since, unlike fish and shrimp, it is nonmobile after setting and the larval stage is likely to be more sensitive than fingerling fish or juvenile shrimp.

6/ EPA may require both fish and invertebrate studies to support paper and pulp mill, cooling tower, and oil water system uses pending the outcome of the aquatic monitoring study.

TABLE A-2
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE HYDROCHLORIDE

§158.145 Wildlife and Aquatic Organisms - Continued

7/ Reserved pending results of fish early life stage and invertebrate life cycle tests.

8/ Registrants must monitor DGH in industrial effluents and receiving waters where it is used in cooling towers, pulp and paper mills, and oil operations and there is also a likelihood of effluent discharges to aquatic ecosystems. Based on the relevant factors (i.e. geographic sites, amount AI used, etc.) registrants must develop acceptable protocols within 3 months to sample a representative number of the above facilities. EPA is requiring this data to assess effect of DGH to endangered aquatic species and chronic effects to aquatic biota. Registrants must consider the following requirments when developing protocol: (i) the samples should be analyzed for DGH, (ii) use of standard methods (i.e. HPLC or MSGC) to measure DGH, (iii) sites selected for sampling should be where DGH is currently being used and be representative of small and large facilities and/or volumes, iv) sites selected must also be representative of a range in volume of the receiving waters and freshwater and estuarine systems, v) sampling should be performed at regular intervals for a long enough period to account for such things as seasonal and use variations.

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPTHALATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibiographic Citation	Must Additional Data Be Submitted?	Time Frame For Submission
158.120 Product Chemistry Product Identity and Composition:						
61-1 - Product Identity & Disclosure of Ingredients	TGAI	All	No		Yes[1]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No		Yes[2]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No		Yes[3]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No		Yes[4]	12 Months
61-2 - Certification of Limits	TGAI	All	No		Yes[5]	12 Months
62-3 - Analytical Methods	TGAI	All	No		Yes[6]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No		Yes	6 Months

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibiographic Citation	Must Additional Data Be Submitted	Time Frame For Submission
63-3 - Physical State	TGAI	All	No		Yes	6 Months
63-4 - Odor	TGAI	All	No		Yes	6 Months
63-5 - Melting Point	TGAI	All	No		Yes	6 Months
63-6 - Boiling Point	TGAI	All	No		Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No		Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	No		Yes	6 Months
63-9 - Vapor Pressure	PAI	All	No		Yes	6 Months
63-10 - Dissociation Constant	PAI	All	No		Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	No		Yes	6 Months
63-12 - pH	TGAI	All	No		Yes	6 Months
63-13 - Stability	TGAI	All	No		Yes	6 Months
Other Requirements						
64-1 - Submittal of samples	N/A		N/A		No	

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

1/ The registrant must submit the empirical formula, the molecular weight, the identity of the producer of the compound, and any names and code numbers by which dodecylguanidine terephthalate is identified.

2/ Registrants must submit data of the manufacturing process, including the relative amounts of beginning material a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures and quality control measursures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

3/ The registrant must provide a discussion impurity, including any N-nitroso compounds, believe to be present at ≥ 0.1% (≥ 1 ppm in the case of nitrosamines) based on knowledge of the beginning material, all possible chemical reactions and any contamination.

4/ Registrants must analyze 5 or more representative samples for the amount of AI and each impurity or intentionally added inert ingredient present for which a certified limit is required (greater than 0.1%). Validated analytical methods must be used.

5/ Upper and lower limits for DGT and for each intentionally added ingredient, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified. In the case of nitrosamines, two samples of each product must be analyzed shortly after production, 3 months after production and 6 months after production. Validated methods (sensitive to to 1.0 ppm in the case of N-nitroso compounds must be used. An upper limit must be provided and certified for all nitroso compounds found.

6/ The registrants must submit quantitative methods to determine DGH. The method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE 1/

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibiographic Citation	Must Additional Data Be Submitted	Time Frame For Submission
§158.130 Envionmental Fate						
DISSIPATION STUDIES LAB:						
161-1 - Hydrolysis	TGAI or PAIRA		No		No	
Photodegradation						
161-2 - In Water	TGAI or PAIRA		No		No	
161-3 - On soil	TGAI or PAIRA		No		No	
161-4 - In Air	TGAI or PAIRA		No		No	
METABOLISM STUDIES LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA		No		No	
162-2 - Anaerobic Soil	TGAI or PAIRA		No		No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA		No		No	
162-4 - Aerobic Aquatic	TGAI or PAIRA		No		No	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA		No		No	
163-2 - Volatility (Lab)	TEP		No		No	
163-3 - Volatility (Field)	TEP		No		No	

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibiographic Citation	Must Additional Data Be Submitted	Time Frame For Submission
§ 158.130 Envionmental Fate - Continued						
DISSIPATION STUDIES FIELD:						
165-1 - Soil	TEP		No		No	
164-2 - Aquatic (Sediment)	TEP		No		No	
164-3 - Forestry	TEP		No		No	
164-4 - Combination and Tank Mixes	2/		No		No	
165-5 - Soil, Long-term	TEP		No		No	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA		No		No	
165-2 - Rotational Crops (Field)	TEP		No		No	
165-3 - Irrigated Crops	TEP		No		No	
165-4 - In Fish	TGAI or PAIRA		No		No	
165-5 - In Aquatic nontarget Organisms	TEP		No		No	

1/ EPA is not requiring environmental fate data for DGT because there are no outdoor use sites registered for this chemical.

2/ This Standard is for single AI formulations only.

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Oral LD_{50} - Rat	TGAI		No		Yes	9 Months
81-2 - Dermal LD_{50}	TGAI		No		Yes	9 Months
81-3 - Inhalation LC_{50} - Rat	TGAI		No		Yes	9 Months
81-4 - Eye Irritation - Rabbit	TGAI		No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI		No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI		No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI		No		No 1/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI		No		Yes	15 Months
- Non-rodent	TGAI		No		Reserved 2/	

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
82-2 - 21-Day Dermal	TGAI		No		Reserved 2	
82-3 - 90-Day Dermal	TGAI		No		No 3/	
82-4 - 90-Day Inhalation: - Rat	TGAI		No		No 4/	
82-5 - 90-Day Neurotoxicity: Hen/Mammal	TGAI		No		No 1/	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI		No		Reserved 2/	
- Non-rodent	TGAI		No		Reserved 2/	
83-2 - Oncogenicity - 2 species: - Rat (preferred), and	TGAI		No		Reserved 2/	
- Mouse (preferred)	TGAI		No		Reserved 2/	
83-3 - Teratogenicity - 2 species:	TGAI		No		Reserved 2/	
83-4 - Reproduction 2-generation	TGAI		No		Reserved 2/	

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI		No		Reserved 2/	
84-2 - Chromosomal Aberration	TGAI		No		Reserved 2/	
84-4 - Other Mechanisms of Mutagenicity	TGAI		No		Reserved 2/	
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA		No		Reserved 2/	

1/ Dodecylguanidine terephthalate, by virtue of its structure or known toxicity, does not require a delayed neurotoxicity study.

2/ Data requirement will be based on comparison of results of required studies to results for dodine to determine if effects are comparable and if data on dodine can be considered equivalent.

3/ Uses do not involve purposeful, prolonged, or comparable exposure.

4/ Repeated inhalation exposure at toxic concentrations are not expected.

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	D	No		No 1/	
71-2 - Avian Dietary LC_{50}	TGAI	D	No		Yes 1/	9 Months
71-3 - Wild Mammal Testing	TGAI	D	No		No	
71-4 - Avian Reproduction	TGAI	D	No		No	
71-5 - Simulated and Actual Field Testing Mammals and Birds	TEP	D	No		No	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}	TGAI	D	No		Yes 2/	9 Months
	TEP 4/	D 3/	No		Yes	9 Months
72-2 - Acute Invertebrate LC_{50}	TGAI	D	No		Yes	9 Months
	TEP 4/	D 3/	No		Yes	9 Months

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-3 - Estuarine and Marine Organism LC_{50}						
- Fish	TGAI	D	No		Reserved 5/	
	TEP 5/	D 3/	No		Reserved 5/	
- Shrimp	TGAI	D	No		Reserved 5/	
	TEP 5/	D 3/	No		Reserved 5/	
- Oyster	TGAI	D	No		Yes	12 Months
	TEP 4/	D 3/	No		Yes	12 Months
72-4 - Fish Early Life Stage, and Invertebrate Life Cycle						
- Freshwater	TGAI	D	No		Reserved 6/	
- Estuarine	TGAI	D	No		Reserved 6/	
72-5 - Fish - Life-Cycle	TGAI	D	No		Reserved 7/	
72-6 - Aquatic Organism Accumulation	TEP	D	No		No	

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	D	No		Yes 8/	24 Months (protocol- 3 months)

1/ For an aquatic nonfood use, only a single dietary study, preferably on the mallard duck, is required.

2/ EPA is initially requiring testing on only a single fish species. If the study demonstrates that DGT toxicity is significantly different from that of dodine, EPA may require testing on a second species.

3/ Required to support uses in paper and pulp mills, cooling towers, and oil water systems and uses that may result in direct discharge of effluent containing pesticide residue.

4/ The typical end-use product used should contain 10% dodecylguanidine terephthalate.

5/ Studies on dodine will suffice unless the results of the 48 hour oyster larvae study on DGT are an order of magnitude different from the same study using dodine. The oyster larvae study will serve as the comparative estuarine organism since, unlike fish and shrimp, it is nonmobile after setting and the larval stage is to be more sensitive than fingerling fish or juvenile shrimp.

6/ EPA may require both fish and invertebrate studies to support paper and pulp mill, cooling tower, and oil water system uses pending the outcome of the monitoring study.

TABLE A-3
GENERIC DATA REQUIREMENTS FOR DODECYLGUANIDINE TEREPHTHALATE

§158.145 Wildlife and Aquatic Organisms - Continued

7/ Reserved pending results of fish early life stage and invertebrate life cycle tests.

8/ Registrants must monitor DGT in industrial effluents and receiving waters where it is used as a biocide in textile manufacturing and there is a likelihood of effluent discharges to aquatic ecosystems. Based on relevant factors (i.e. geographic sites, amount AI used, etc.) registrants must develop acceptable protocols within 3 months to sample a representative number of textile facilities. EPA is requiring this data to assess effects of DGT to endangered aquatic species and chronic effects to aquatic biota. Registrants must consider the following when developing protocols; (i) the samples should be analyzed for DGT; (ii) use of standard methods (i.e. HPLC or MSGC) to measure DGT, (iii) sites selected for sampling should be where DGT is currently being used and be representative of small and large facilities an must also be representative of a range in volume of the receiving waters and freshwater and estuarine systems; v) sampling should be performed at regular intervals for a long enough period to account for such things as seasonal and use variations.

TABLE B-1
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DODINE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	Yes	Desk references 1/	No	
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	Partially	00101353 00101403 00143591	Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	Partially	00143591	Yes 3/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No		Yes 4/	12 Months
62-2 - Certification of Limits	MP	All	No		Yes 5/	12 Months
62-3 - Analytical Methods	MP	All	Partially	00143591	Yes 6/	12 Months
Other Requirements:						
64- 1 - Submittal of samples	MP	All	No		No	6 Months

TABLE B-1
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DODINE

1/ Information obtained from the following desk references: Acceptable Common Names and Chemicals Names for the Ingredient Statement on Pesticide Labels 4th Ed., 1979, p. 113 U.S. EPA, EPA-540/9-77-017; Farm Chemicals Handbook, 1986, p. C 91 Meister Publishing Co., Willoughby, Ohio; Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, Marshall Sittig (Ed.), Noyes Data Corp. p. 354; The Pesticide Manual: A World Compendium, 7th ed., Worthing and Walker (Eds.), British Crop Protection Council, 1983, p. 229.

2/ The registrant must submit details of a manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process purification procedures and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

3/ The registrant must provide a discussion of each impurity, including any N-nitroso compounds, believed to be present at ≥ 0.1% (≥ 1 ppm in the case of nitrosamines) based on knowledge of the beginning materials, all possible chemical reactions and any contamination.

4/ Registrants must analyze 5 or more representative samples for the amount of AI and each impurity or intentionally added inert ingredient present for which a certified limit is required (greater than 0.1%). Validated analytical methods must be used.

5/ Upper and lower limits for dodine and for each intentionally added inert ingredient, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified. In the case of nitrosamines, two samples of each product must be analyzed shortly after production, 3 months after production, and 6 months after production. Validated methods (sensitive to 1.0 ppm in the case of N-nitroso compounds) must be used. An upper limit must be provided and certified for all N-nitroso compounds found.

6/ The registrant must submit quantitative methods to determine dodine (confirmatory). The method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE B-1
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DODINE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Oral Toxicity - Rat	MP	All	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	No		Yes	9 Months
81-3 - Acute Inhalation Irritation - Rat	MP	All	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	No		Yes	9 Months

TABLE B-2
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DODECYLGUINIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	Partially	Desk references 1/	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	Partially		Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No		Yes 3/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No		Yes 4/	12 Months
63-2 - Certification of Limits	MP	All	No		Yes 5/	12 Months
63-3 - Analytical Methods	MP	All	No		Yes 6/	12 Months
Other Requirements:						
64-1 - Submittal of Samples	MP	ALL	No		No	6 Months

TABLE B-2
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DODECYLGUANIDINE HYDROCHLORIDE

§158.120 Chemistry - Footnotes

1/ Information obtained from the following desk references: Acceptable Common Names and Chemicals Names for the Ingredient Statement on Pesticide Labels 4th Ed., 1979, p. 113 U.S. EPA, EPA-540/9-77-017; Farm Chemicals Handbook, 1986, p. C 91 Meister Publishing Co., Willoughby, Ohio; Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, Marshall Sittig (Ed.), Noyes Data Corp. p. 354; The Pesticide Manual: A World Compendium, 7th ed., Worthing and Walker (Eds.), British Crop Protection Council, 1983, p. 229.

2/ The registrant must submit details of a manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process purification procedures and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

3/ The registrant must provide a discussion of each impurity, including any N-nitroso compounds, believed to be present at $\geq$ 0.1% ($\geq$ 1 ppm in the case of nitrosamines) based on knowledge of the beginning materials, all possible chemical reactions and any contamination.

4/ Registrants must analyze 5 or more representative samples for the amount of AI and each impurity or intentionally added inert ingredient present for which a certified limit is required (greater than 0.1%). Validated analytical methods must be used.

5/ Upper and lower limits for dodine and for each intentionally added inert ingredient, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified. In the case of nitrosamines, two samples of each product must be analyzed shortly after production, 3 months after production, and 6 months after production. Validated methods (sensitive to 1.0 ppm in the case of N-nitroso compounds) must be used. An upper limit must be provided and certified for all N-nitroso compounds found.

6/ The registrant must submit quantitative methods to determine dodine (confirmatory). The method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE B-2

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DODECYLGUANIDINE HYDROCHLORIDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicity						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	All	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	All	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbits	MP	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	No		Yes	9 Months

TABLE B-3

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DODECYLGUANIDINE TEREPHTHALATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No		Yes 1/	
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No		Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No		Yes 3/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No		Yes 4/	12 Months
62-2 - Certification of Limits	MP	All	No		Yes 5/	12 Months
62-3 - Analytical Methods	MP	All	No		Yes 6/	12 Months
Other Requirements						
64-1 - Submittal of Samples	MP	All	No		No	6 Months

TABLE B-3
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DODECYLGUANIDINE TEREPHTHALATE

1/ The registrant must submit the empirical formula, the molecular weight, the identity of the producer of the compound and any names and code numbers by which dodecylguanidine terephthalate is identified.

2/ The registrant must submit details of the manufacturing process, including the relative amounts of beginning material a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process purification procedures and quality control measures, the name and address of the manufacturer, producer or supplier of each beginning material used, and a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties.

3/ The registrant must provide a discussion of each impurity, including any N-nitroso compounds, believed to be present at ≥ 0.1% (≥ 1 ppm in the case of of nitrosamines) based on knowledge of the beginning material, all possible chemical reactions and any contamination.

4/ Registrants must analyze 5 or more representative samples for the amount of AI and each impurity intentionally added inert ingredient present for which a certified limit is required (greater than 0.1%). Validated analytical methods must be used.

5/ Upper and lower limits for DGT and for each intentionally added inert ingredient, and upper limits for each impurity present at 0.1% (w/w) must be provided and certified. In the case of nitrosamines, two samples of each products must be analyzed shortly after production, 3 months after production and 6 months after production. Validated methods (sensitive to to 1.0 ppm in the case of N-nitroso compounds) must be used. An upper limit must be provided and certified for all N-nitroso compounds found.

6/ The registrants must submit quantitative methods to determine DGT. The method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE B-3

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING DODECYLGUANIDINE TEPEPHTHALATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation Submitted	Must Additional Data be Submission	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	All	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	All	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	No		Yes	9 Months

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

SUMMARY-3

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

SUMMARY-5

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

EPA Compendium of Acceptable Uses

DODINE

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DODINE*

TYPE PESTICIDE: Fungicide, Antimicrobial, Algaecide

FORMULATIONS:
Tech (98.9%)
FI (75%, 95%)
D (1%, 2%, 3%, 3.9%, 4%, 5%, 6%)
WP (22.5%, 65%)
WP/D (95%)
RTU (4.7%, 4.8%, 5%, 9%, 10%, 0.79 lb/gal or 10%, 0.84 lb/gal or 10%)

GENERAL WARNINGS AND LIMITATIONS: Dodine is compatible with commonly used fungicides, insecticides, and acaricides such as dimethoate, diazinon, dinocap, ferbam, phosmet, propargite, sulfurs, zineb, and wettable powder formulations of azinphos-methyl, carbaryl, chlorbenside, dicofol, endosulfan, malathion, phosphamidon, parathion, ryanodine, and slow breaking oils of 60 to 75 viscosity. Compatibility should be checked prior to use with emulsifiable concentrate or flowable concentrate formulations. Dodine is not compatible with chlorobenzilate, Bordeaux mixture, fixed copper, chlordimeform, lime or lime sulfur. Dodine-oil mixtures are compatible with liquid concentrate and flowable concentrate formulations of phosphate insecticides as are wettable powder formulations of parathion, azinphos-methyl, carbophenothion, and certain other insecticides. Check compatibility prior to use. Dodine-oil mixtures are not compatible with wettable powder formulations of malathion, carbaryl, zineb, ferbam, and sulfurs. The 65 percent wettable powder formulation may be applied in concentrate sprays except as noted. Dusts may be applied by aircraft.
Do not graze cover crops in treated orchards.
Precautionary Statements. For agricultural uses - aerial and ground (airblast) applications - fruit fungicide (liquid, dust, and other formulations applied as sprays): During mixing/loading of the concentrate, wear a long-sleeved shirt, long-legged pants (or coveralls), chemical-resistant gloves, chemical-resistant shoes, shoe covers, or boots, chemical-resistant apron, and goggles or face shield. During application of the product, wear the same protective clothing, except that a chemical-resistant hat with a wide brim must be worn and the chemical-resistant apron need not be worn. The applicator using an enclosed tractor cab with positive pressure filtration or an enclosed cockpit must wear long pants or coveralls, long-sleeved shirt, socks and shoes. During aerial application in a non-enclosed cockpit, a helmet with a visor may be substituted for the hat and goggles; chemical-resistant shoes, shoe coverings, or boots may be omitted.
For dust formulations - agricultural uses: Mixer/loader/applicators must wear long-sleeve shirt, long-legged pants (or coveralls), socks, shoes, chemical-resistant gloves plus any existing label-required protection.
Do not enter or allow entry into treated areas until [sprays have dried/dusts have settled/vapors have dispersed, as applicable] to perform hand labor tasks. Workers must wear a long-sleeved shirt,

*dodecylguanidine acetate

GENERAL WARNINGS AND LIMITATIONS (continued)

long-legged pants (or coveralls), chemical-resistant gloves, socks, and shoes for early reentry into treated areas to perform other tasks before [sprays have dried, dusts have settled, or vapors have dispersed].
Refer to Registration Guidance Package for further precautionary statements.
Wear goggles or face shield and chemical resistant gloves when handling industrial formulations.
Observe all warnings and limitations for other active ingredients on multiple active ingredient labels or in tank mixes.
Dosage rates are given in active ingredient.
Agricultural Crop Tolerances (other than those listed in the text):

Meat	0.0 ppm
Milk	0.0 ppm
Spinach	12.0 ppm

Definition of Terms:
MAI - multiple active ingredient(s)
SLN - Special Local Needs (24-C)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/04001AA	Apple		5 ppm 5 day preharvest interval through 0.49 pound per 100 gallons or 1.3 pounds per acre for wettable powder or 1.6 pounds per acre for dust formulations. 7 day preharvest interval through 1.95 to 2.0 pounds per acre. Do not use treated apples in the manufacture of apple pomace for use in livestock feeds. May cause russetting on Golden Delicious, Grime Golden, and Rhode Island Greening apple varieties. Freezing or near-freezing temperatures, particularly when accompanied by slow-drying conditions may injure apple fruit or predispose the fruit to chemical injury. Do not apply more than 1.3 pounds per acre (wettable powder) immediately before, during, or immediately after occurrence of such conditions.
FEAJVAG	Apple scab (Venturia)	0.081-0.49 lb/100 gal or 0.65-1.95 lb/A (65% WP) 000241-00051 or 0.6-2.0 lb/A (1%, 2%, 3%, 4%, 6% D) 007001-00205 or	Delayed dormant and foliar applications. Protective schedule: Using ground equipment, apply 0.16 to 0.325 pound per 100 gallons or 0.65 to 1.3 pounds per acre of wettable powder at 5 to 7 day intervals or as needed from prebloom through first cover. Aply 0.081 to 0.16 pound per 100 gallons or 0.65 pound per acre in subsequent cover sprays as needed. May be applied in a delayed dormant oil schedule at 0.65 to

DODINE

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Apple (continued)		
	0.02-0.025 lb/mature tree (1% D) [MAI] 0.45 lb/500 gal (22.5% WP) or 0.6-1.95 lb/A (2%, 3.9%, 4%, 5.2% D)	1.3 pounds per acre with 2 gallons of 60 to 75 viscosity oil. By aircraft, apply 0.975 pound per acre in 5 to 7 gallons per acre as above. Post infection applications: After an infection period has occurred, apply 0.49 pound per 100 gallons or 1.95 pounds per acre (wettable powder) during or following a rain from prebloom through first cover, and in later cover sprays as needed. While timing of the spray may vary considerably depending upon temperatures, it is recommended that application be made within 36 hours from the beginning of the rain or wet period which caused the infectrion. Emergency scab conditions: If leaf lesions are visible during prebloom, thoroughly apply a dilute spray of 0.325 pound per 100 gallons, repeat in 5 to 7 days then follow protective schedule. If leaf lesions are visible following bloom, thoroughly apply a dilute spray of 0.325 pound per 100 gallons, repeat in 7 to 10 days then follow protective schedule. Apply dusts using ground equipment or aircraft as above on a protective schedule. May be formulated with glyodin; ferbam and sulfur; parathion and sulfur; or sulfur and captan.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/03012AA	Black Walnut		0.3 ppm No preharvest interval through 0.65 pound per 100 gallons or 2.6 pounds per acre. Do not graze meat or dairy animals in treated groves.
FAAAGAT	Anthracnose (leaf spot) (Gnomonia)	0.65 lb/100 gal or 2.6 lb/A (65% WP)	Delayed dormant and foliar applications. Apply when first leaves unfold. Repeat at 10 to 14 day intervals.
/05002AA	Cherry		5 ppm (sour and sweet) No preharvest interval through 0.325 pound per 100 gallons or 1.3 pounds per acre for wettable powder or 2.5 pounds per acre for dust formulations. Application when temperatures and humidity are excessively high may cause spotting to foliage or fruit.
IBAOMCB	Brown rot blossom blight (Monilinia)	0.325 lb/100 gal or 1.3 lb/A (65% WP)	Use limited to western states. Foliar application. Apply when petals begin to open. Repeat at full bloom and again at petal fall.
FMBCCDJ	Cherry leaf spot (Coccomyces)	0.16-0.325 lb/100 gal or 0.65-1.3 lb/A (65% WP) or 0.8-2.4 lb/A (3%, 4%, 6% D) [MAI] 0.45 lb/500 gal (22.5% WP) or 0.8-1.2 lb/A (4% D)	Foliar and postharvest applications. Apply at petal fall or when first leaves unfold. Repeat at 7 to 10 day intervals and continue through harvest if conditions favor leaf spot. Apply immediately after harvest and as needed. May be formulated with glydoin; or parathion and sulfur.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/05004AA	Peach		5 ppm Do not apply after delayed dormant through 1.3 pounds per 100 gallons or 2.6 pounds per acre, or after petal fall through 0.325 pound per 100 gallons or 1.3 pounds per acre in western states. 15 day preharvest interval through 1.3 pounds per acre for tank mix with captan.
FMCBXAA	Bacterial spot (Xanthomonas)	1.3 lb/A or 0.325 lb/100 gal (65% WP)	Foliar application. Tank mix with captan (2.0 pound active ingredient captan per acre or 0.5 pound per 100 gallons). Under light to moderate disease conditions, apply at shuck split and repeat at 7 to 10 day intervals through the cover sprays. Do not use concentrate sprays higher than 3X. Do not combine with solvent formulations of insecticides or sulfur. Spray injury may result if the tank mix is applied with, immediately before, or closely after an oil or zinc sulfate-lime spray.
FBADMCB	Brown rot blossom blight (Monilinia)	0.325 lb/100 gal or 1.3 lb/A (65% WP)	Use limited to western states. Foliar application. Apply when petals begin to open. Repeat at full bloom and again at petal fall.
FEAGTAB	Leaf curl (Taphrina)	0.65-1.3 lb/ 100 gal or 2.6 lb/A (65% WP)	Use limited to western states. Dormant and delayed dormant applications. Apply high rate just before buds swell in the spring. If leaf curl was moderate to sever the previous season, apply 1 month before buds swell in the spring and again just prior to bud swell.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04003AA	Pear		5 ppm 5 day preharvest interval through 1.6 pounds per acre as a dust. 7 day preharvest interval through 0.49 pound per 100 gallons or 1.95 to 2.0 pounds per acre.
FEAJVAG	Pear scab (Venturia)	0.325-0.49 lb/100 gal or 1.3-1.95 lb/A (65% WP) 000241-00051 or 0.75-2.0 lb/A (2%, 3%, 4%, 6% D)	Delayed dormant and foliar applications. Apply at 5 to 7 day intervals or as needed from prebloom through petal fall again in first cover. Repeat in subsequent sprays as needed. In OR, wettable powder may be applied by aircraft in 5 to 7 gallons of spray per acre on the above schedule. Apply dusts using ground equipment or aircraft on above schedule.
		[MAI] 0.8-1.2 lb/A (4% D)	May be formulated with parathion and sulfur.
		[SLN] up to 1.3 lb/A (65% WP)	SLN - Use limited to CA. Delayed dormant and foliar applications. Apply by aircraft in not less than 10 gallons per acre. Apply 8 times per year.
/03008AA	Pecan		0.3 ppm Do not apply after shucks have started to open through 4.55 pounds per acre. Do not graze meat or dairy animals in treated groves. Severe folige injury has been experienced on Moore and Van Deman varieties in the southeast.
FMBCCBM	Brown leaf spot (Cercospora)	0.325-0.65 lb/100 gal [max 700 gal/A] or 1.3-2.6 lb/A (65% WP)	Delayed dormant and foliar applications. Apply when first leaves are showing and repeat at 10 to 14 day intervals through first cover. Repeat at 2 to 3 week intervals or as needed. By aircraft, apply 1.3 pounds per acre (or 2.6 pounds per acre under severe scab conditions) in a minimum of 20 gallons of spray.
FMASMCO	Downy leaf spot (Mycosphaerella)		
FCADMCO	Leaf blotch (Mycosphaerella)		
FMBDGAT	Liver spot (Gnomonia)		
FEAJCCV	Pecan scab (Cladosporium)		

DODINE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01016AA	Strawberry		5 ppm 14 day preharvest interval through 1.3 pounds per acre.
FBATDAH	Leaf blight (Dendrophoma)	0.9-1.3 lb/A (65% WP) (1%, 4% D) or 0.02-0.025 lb/1,000 sq.ft (1% D)	Delayed dormant and foliar applications. Apply as soon as new growth starts and repeat at weekly intervals. Apply wettable powder in sufficient water for thorough coverage (250 to 300 gallons).
FGAKDBS	Leaf scorch (Diplocarpon)		
FMBCMCO	Leaf spot (Mycosphaerella)		
	TERRESTRIAL NONFOOD CROP		
	(Ornamental Plants and Forest Trees		
/35056AA	Flowering Crabapple		
FEAJVAG	Apple scab (Venturia)	0.6-0.8 lb/A or 0.02-0.025 lb/mature tree (1% D)	Delayed dormant and foliar applications. Apply during prebloom. Repeat at 5 to 7 day intervals through first cover.
/34120AA	Rose		Higher dosages may cause stunting and foliation on first year plants and chlorosis on older established plants.
FMAEDBS	Black spot (Diplocarpon)	0.3-0.4 lb/A (1%, 4% D) or 0.0075-0.01 lb/1,000 sq.ft (1% D)	Foliar application. Apply when young leaves first appear. Repeat at 7 to 10 day intervals throughout the season. Dust lightly but thoroughly.
/35119AA	Sycamore		
FAAAGAT	Anthracnose (Gnomonia)	0.65-0.975 lb/100 gal (65% WP)	Delayed dormant and foliar applications. Apply at high rate when buds start to swell. Repeat at low rate when buds break open and again 10 to 14 days later.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	AQUATIC NONFOOD		
	(Aquatic Sites)		
	Brewery Pasteurizer Water		See Commercial and Industrial Recirculating Water Cooling Systems.
/65019MA	Commercial and Industrial Recirculating Water Cooling Systems		Systems which are heavily contaminated must be cleaned before treatment. Dosage will depend on the condition of the system prior to treatment.
PKAAAAA	Algae	0.01-0.3 lb/ 1,000 gal system water (5%, 10% RTU)	Water treatment (1.2 to 36 ppm active ingredient). Apply to the cleaned system or when growth is first noticed. Initial dose: Apply 0.2 to 0.3 pound (24 to 36 ppm) continuously; or apply once, twice, or three times weekly or as needed. Subsequent dose: When control is evident, apply 0.01 to 0.2 pound (1.2 to 24 ppm) as a continuous treatment daily or every 3 days as needed.
DBABAAA	Slime-forming bacteria		
FYAFQBB	Slime-forming fungi		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65019MA /65005MA	(evaporative condensers, heat exchanger water systems, commercial and industrial cooling towers, influent systems such as flow through filters, ponds, lagoons, industrial water scrubbing systems, and brewery pasteurizers)		
PKAAAAA	Algae	0.01-0.4 lb/ 1,000 gal system water (10% RTU)	Water treatments (1.2 to 48 ppm active ingredient). Slug or intermittent method. Initial dose: When system is noticeably fouled, apply 0.05 to 0.4 pound (6 to 48 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.01 to 0.2 pound (1.2 to 24 ppm) every 3 days or as needed. Continuous method. Initial dose: When the system is noticeably fouled, apply 0.05 to 0.4 pound (6 to 48 ppm). Continue until control is achieved. Subsequent dose: When control is evident, continuously feed to maintain a dosage of 0.01 to 0.2 pound (1.2 to 24 ppm) per 1,000 gallons of blowdown (or water loss) from the system.
DBABAAA	Slime-forming bacteria		
FYAFQBB	Slime-forming fungi		
/65025MA	Oil Field Water Systems (oil field water, polymer, or mycellar floods, water disposal systems or other oil field water systems)		Do not apply in marine and/or estuarine oil fields. Badly fouled systems should be cleaned prior to treatment. Dosage will depend on the condition of the system prior to treatment.
PKAAAAA	Algae	1.0-10.0 lb/ 1,000 bbl water (10% RTU)	Water treatment (3.0 to 30 ppm active ingredient). Slug or intermittent method. Initial dose: When the system is noticeably fouled, apply 1.0 to 10.0 pounds (3.0 to 30 ppm) intermittently for 4 to 8 hours per day and from 1 to 4 times per week or as needed. Repeat until control is achieved. Subsequent dose: When control is evident, apply 1.0 to 7.5 pounds (3.0 to 22.5 ppm) every 3 days or as needed.
DBABAAA	Slime-forming bacteria		
DBAEAAA	Sulfate reducing bacteria		
FYAFQBB	Slime-forming fungi		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Oil Field Water Systems (oil field water, polymer, or mycellar floods, water disposal systems or other oil field water systems) (continued)		
			Continous method. Initial dose: When the system is noticeably fouled, apply 1.0 to 10.0 pounds (3.0 to 30 ppm). Continue until control is achieved. Subsequent dose: When control is evident, continuously feed to maintain a dosage of 1.0 to 7.5 pounds (3.0 to 22.5 ppm).
/65008MA	Pulp and Paper Mill Systems		
			Apply directly to the pulp and paper mill system at a point where the formulation will be uniformly mixed.
DBABAAA FYAFQBB	Slime-forming bacteria Slime-forming fungi	[MAI] 0.007-0.094 lb/ST pulp or paper produced [3.5-47 ppm a.i.] or 0.0047-0.094 lb/1,000 gal additive system [0.56-11 ppm a.i.] (4.7% RTU)	Water treatment. Use intermittent or slug method, or continuous method. Initial dose: When the system is noticeably fouled, apply 0.007 to 0.094 pound per ton. Repeat until control is achieved. Subsequent dose: When control is evident, apply initial rate as needed to maintain control. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
		[MAI] 0.0048-0.048 lb/ST pulp or paper produced [2.4-24 ppm a.i.] or 0.0048-0.19 lb/1,000 gal additive system [0.58-23 ppm a.i.] (4.8% RTU)	Water treatment. Slug or intermittent method. Initial dose: When system is noticeably fouled, apply 0.0048 to 0.048 pound per ton (2.4 to 24 ppm); apply 0.024 to 0.19 pound per 1,000 gallons (2.9 to 23 ppm) directly to the additive system. Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.0048 to 0.024 pound per ton (2.4 to 12 ppm) as needed to maintain control. Treat the additive system at 0.012 to 0.096 pound (1.4 to 11.5 ppm).

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Pulp and Paper Mill Systems (continued)		
			Continuous method. Initial dose: Apply as in slug or intermittent method. Subsequent dose: When control is evident, continuously feed to maintain a dosage of 0.0048 to 0.014 pound per ton; and apply 0.048 to 0.072 pound per 1,000 gallons (0.58 to 8.6 ppm) to the additive system. Formulated with methylene, bis-(thiocyanate).
	INDOOR		
	(Industrial Preservatives and Additives)		
/810070A	Metalworking Cutting Fluids soluble cutting oil, semi-synthetic and synthetic type metalworking fluids, hydraulic fluids, and chemical coolants)		
DBADAAA	Deterioration/ spoilage bacteria	[MAI] 0.0045-0.0135% a.i. by volume of diluted cutting fluid or 0.041-0.12 lb/100 gal of diluted cutting fluid (9% RTU)	Preservative incorporation. Formulated with hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine.
DBABAAA	Slime-forming fungi		
DBAEAAA	Sulfate-reducing bacteria		
FYAIOBB	Fungi		

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/810080A	Oil Recovery Drilling Fluids (packer fluids and drilling muds)		Do not apply in marine and/or estuarine oil fields.
DBABAAA	Slime-forming bacteria	5.0-50.0 lb/ 1,000 bbl or 8.0-80 ppm a.i. (10% RTU)	Additive incorporation. Add directly to the packer fluid or drilling mud. The dosage rate will depend upon the severity of the contamination.
DBAEAAA	Sulfate-reducing bacteria		
/810100A	Paper and Paper Products		
A24	Bacteriostat	up to 0.4% a.i. by weight of paper or paperboard (95% WP/D) or up to 0.8% a.i. by weight of paper or paperboard (95% WP/D)	Preservative incorporation. Formulation may be added to the pulp stock in the beater or applied to the formed sheet by size press or rollcoater, or as a uniform spray. Food packaging. Apply in accordance with 21 CFR, Section 176.170: For use only in paper and paperboard to be in contact with aqueous and fatty nonalcoholic foods having a pH above 5 at a level not to exceed 0.4 percent active ingredient by weight of the paper or paperboard; or, for use in the outer ply of multiwall paper bags for contact with dry foods (dry solids with the surface containing no free fat or oil) at a level not to exceed 0.8 percent active ingredient by weight of the paper. Industrial or agricultural paper and paperboard products. Add up to 0.8 percent active ingredient by weight of paper or paperboard when paper or paperboard product is to be subjected to excessive leaching as by rainfall or contact with ground water.
FYADQBB	Fungi		
FYAHQBB	Yeasts		

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DODINE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/810160A /810010A /810020A	Preservation of Pulp and Paper Mill Processing Chemicals, Adhesives, and Coatings		
A24	Bacteriostat	[MAI] 9.4-48 ppm a.i. (4.7%, 4.8% RTU)	Preservative incorporation. Add directly to the material to be preserved prior to manufacturing into the finished product, i.e., pulp, broke, polymers, defoamers, alum, emulsions, adhesives, paper mill coatings, pigment slurries, and paper products. The dosage rate will depend upon the material to be preserved and the storage time. The usual addition should be 9.4 to 14 ppm. Under extreme conditions of spoilage, the dosage rate should be increased to 12 to 38 ppm. The above recommendations are based on a maximum storage time of 2 weeks. For storage greater than 2 weeks, the maximum concentration should be increased to 48 ppm. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16); or, methylene bis(thiocyanate).
FYADQBB	Fungi		

AERIAL AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops)	Apple, Cherry, Pear, Pecan, Strawberry
		TERRESTRIAL NONFOOD CROP (Ornamental Plants and Forest Trees)	Flowering Crabapple, Rose
9900300 AAAAAAA	Tank Mix		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops)	Peach

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DODINE

Listing of Registered Pesticide Products by Formulation

&098.9001 98.9% technical chemical
dodine (044301)
000241-00269

&075.0002 75% formulation intermediate
dodine (044301)
000241-00063

&095.0002 95% formulation intermediate
dodine (044301)
049854-00015

&001.0003 1% dust
dodine (044301)
008590-00165

&002.0003 2% dust
dodine (044301)
000595-00219 002393-00200* 008590-00459
*currently unavailable for review

dodine (044301), parathion (057501) plus sulfur or sulphur (077501)
005481-00297

&003.0003 3% dust
dodine (044301)
000241-00061 000595-00265

&003.9003 3.9% dust
dodine (044301), sulfur or sulphur (077501) plus captan (081301)
005481-00289

&004.0003 4% dust
dodine (044301)
000241-00062 000279-01753 000595-00224 000802-00431
002393-00201 007001-00205 008590-00458 034704-00153

dodine (044301), parathion (057501) plus sulfur or sulphur (077501)
000595-00281

&005.0003 5% dust
dodine (044301), ferbam (034801) plus sulfur or sulphur (077501)
005481-00288

&006.0003 6% dust
dodine (044301)
000595-00299

DODINE

Listing of Registered Pesticide Products by Formulation (continued)

&022.5006 22.5% wettable powder
dodine (044301) plus glyodin (043601)
008590-00277

&065.0006 65% wettable powder
dodine (044301)
000241-00051 002749-00152

CA780042

&095.0007 95% wettable powder/dust
dodine (044301)
049854-00009

&204.7016 4.7% (0.38 lb/gal) liquid-ready to use
dodine (044301) plus alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16) (069105)
045017-00023

&204.8016 4.8% (0.39 lb/gal) liquid-ready to use
dodine (044301) plus methylene bis(thiocyanate) (068102)
045017-00024

&205.0016 5% (0.42 lb/gal) liquid-ready to use
dodine (044301)
009386-00017

&209.0016 9% liquid-ready to use
dodine (044301) plus hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (083301)
001839-00117

&210.0016 10% liquid-ready to use
dodine (044301)
003876-00049

&210.0016 10% (0.79 lb/gal) liquid-ready to use
dodine (044301)
003876-00077 034571-00004 048525-00005

&210.0016 10% (0.84 lb/gal) liquid-ready to use
dodine (044301)
009386-00016

9999999 State Label Registrations

MI Reg. No.
000635-08179

NY Reg. No.
038655-10452

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Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
069105	alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16)	--
081301	captan	--
034801	ferbam	--
043601	glyodin	--
083301	hexahydro-1,3,5-tris(2-hydroxyethyl)-2-triazine	--
068102	methylene bis(thiocyanate)	--
057501	parathion	--
077501	sulfur	sulfur or sulphur

-- Use Common Name

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Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
081301	captan	--

-- Use Common Name

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65035MA	Commercial and Industrial Auxiliary Water Systems - General (such as fire protection systems and pump or screen bays, waste water and waste material disposal, holding or recovery systems such as storage tanks, storage piles, associated piping, settling ponds and lagoons, transport spillways or canals and disposal wells)		Apply by slug or intermittent feed or by spraying onto a waste pile. Additions to water systems should be made during the pumping operation and as close as possible to the pump.
PKAAAAA	Algae	[MAI] 0.0375-0.2 lb/1,000 gal system water (5% RTU)	Water and waste water treatment. When treatment is necessary, apply 0.075 to 0.2 pound per 1,000 gallons of water in the system, or being added to the system, for 4 to 8 hours, 1 to 4 times per week or as needed to achieve desired level of control. When control is achieved, apply 0.0375 to 0.1 pound per 1,000 gallons of water in the system. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
IGAAAAA	Mollusks [Reg. No. 3876-245]		
DBABAAA	Slime-forming bacteria		
FYAFQBB	Slime-forming fungi		
/65019MA	Commercial and Industrial Water Cooling Systems		Systems which are heavily contaminated must be cleaned before treatment. Apply at a point in the system where the formulation will be uniformly mixed. Do not apply in potable water systems.
PKAAAAA	Algae	0.056-0.165 lb/1,000 gal system water (33% RTU)	Water treatment (6.7 to 20 ppm active ingredient). Slug method. Initial dose: When system is noticeably fouled, apply 0.11 to 0.165 pound (13 to 20 ppm) 1 to 3 times per week. Subsequent dose: When control is evident, apply 0.056 to 0.11 pound (6.7 to 13 ppm) once per week or as needed.
IGAAAAA	Mollusks [Reg. No. 3876-145, 5% RTU]		
DBABAAA	Slime-forming bacteria		
FYAFQBB	Slime-forming fungi		

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Commercial and Industrial Water Cooling Systems (continued)		
	0.027-0.17 lb/1,000 gal system water (12.25%, 20% RTU)	Water treatment (3.3 to 20 ppm active ingredient). Slug method. Initial dose: When system is noticeably fouled, apply 0.055 to 0.17 pound (6.6 to 20 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.027 to 0.115 pound (3.3 to 14 ppm) 1 to 3 times per week or as needed to maintain control.
	13-128 fl.oz 5.25% RTU/ 1,000 gal system water (5.25% RTU)	Water treatment (5.25 to 52.5 ppm active ingredient by volume). Slug method. Initial dose: Apply 32 to 128 fluid ounces (13 to 52.5 ppm). Subsequent dose: Apply 13 to 52 fluid ounces (5.25 to 21 ppm) 1 to 2 times per week or as needed. For severe contamination, apply at initial rate.
	[MAI] 0.0044-0.175 lb/1,000 gal water (10.78% RTU)	Water treatment (0.53 to 21 ppm active ingredient). Intermittent or slug method. Initial dose: When the system is noticeably fouled, apply 0.0675 to 0.175 pound (8.0 to 21 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.022 to 0.0875 pound (2.7 to 10.5 ppm) weekly or as needed to maintain control. Continuous method. Initial dose: When the system is just noticeably fouled, apply 0.044 to 0.0875 pound per 1,000 gallons of makeup water (5.25 to 10.5 ppm). Subsequent dose: Maintain initial dose level by continuously feeding 0.0044 to 0.044 pound per 1,000 gallons of water lost by blowdown (0.53 to 5.25 ppm). Formulated with bis(tributyltin) oxide.

DODECYLGUANIDINE HYDROCHLORIDE

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Commercial and Industrial Water Cooling Systems (continued)		
	[MAI] 0.0025-0.1 lb/1,000 gal system water (5%, 10% RTU)	Water treatment (0.3 to 12 ppm active ingredient). For use in evaporative condensers, heat exchange water systems, commercial and industrial cooling towers, influent systems such as flow through filter, lagoons, and industrial water scrubbing systems. *Intermittent or slug method*. Initial dose: When the system is noticeably fouled, apply 0.015 to 0.1 pound (1.8 to 12 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.0075 to 0.075 pound (0.9 to 9.0 ppm) every 3 days (daily for *algae*) or as needed to maintain control. *Continuous method*. Initial dose: When the system is noticeably fouled, apply 0.015 to 0.1 pound (1.8 to 12 ppm). For *algae*, repeat until control is achieved. Subsequent dose: Apply continuously to maintain a dosage of 0.0075 to 0.075 pound (0.9 to 9.0 ppm) for the 10 percent formulation, or 0.0025 to 0.025 pound (0.3 to 3.0 ppm) for the 5 percent formulation. Formulated with methylene bis(thiocyanate); or alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
	[MAI] 0.01-0.2 lb/1,000 gal water (10% RTU)	Water treatment (1.2 to 24 ppm active ingredient). Apply either intermittently or continuously at 0.01 to 0.2 pound per day per 1,000 gallons contained in and/or added to the system (1.2 to 24 ppm). Formulated with bis(trichloromethyl) sulfone and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).

DODECYLGUANIDINE HYDROCHLORIDE

Commercial and Industrial Water Cooling Systems (continued)
(once-through and closed-cycle fresh and sea water cooling systems, cooling ponds, canals, and lagoons)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
PKAAAAA	Algae	[MAI] 0.001-0.05 lb/1,000 gal system water (5% RTU)	Water treatment (0.12 to 6.0 ppm active ingredient). Slug or intermittent method. Initial dose: When the system is noticeably fouled, apply 0.01 to 0.05 pound (1.2 to 6.0 ppm) per 1,000 gallons of water based on the flow rate through the system. Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.01 to 0.75 pound (1.2 to 9.0 ppm) intermittently or as needed to maintain control. Continuous method. Initial dose: When the system is noticeably fouled, apply 0.02 to 0.1 pound (2.4 to 12 ppm) and repeat until control is achieved. Subsequent dose: Continuously feed 0.001 to 0.01 pound (0.12 to 1.2 ppm). Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
IGAAAAA	Mollusks [Reg. No. 003876-00145]		
DBABAAA	Slime-forming bacteria		
FYAFDBB	Slime-forming fungi		

DODECYLGUANIDINE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65025MA	Oil Field Water Systems (oil field water, polymer or mycellar floods, water disposal systems or other oil field water systems)		Do not apply in marine and/or estuarine oil fields. Badly fouled systems should be cleaned prior to treatment. Addition may be made at the free water knockouts before or after the injection pumps and injection well headers.
PKAAAAA	Algae	[MAI] 0.4-7.5 lb/ 1,000 bbl water (10% RTU)	Water treatment (1.1 to 21 ppm active ingredient). Slug or intermittent method. Initial dose: Apply 1.0 to 7.5 pounds (2.8 to 21 ppm) intermittently for 2 to 8 hours per day once per week or daily as needed. Repeat until control is achieved. Subsequent dose: When control is established, apply 0.4 to 7.0 pounds (1.1 to 20 ppm) every 3 days or as needed to maintain control. Continuous method. Initial dose: When the system is noticeably fouled, apply 1.0 to 7.5 pounds (2.8 to 21 ppm). Continue until control is achieved. Subsequent dose: Continuously feed to maintain a dosage of 0.4 to 7.0 pounds (1.1 to 20 ppm. Formulated with methylene bis-(thiocyanate).
DBABAAA	Slime-forming bacteria		
DBAEAAA	Sulfate-producing bacteria		
FYAFOBB	Slime-forming fungi		
FYAHOBB	Yeasts [Reg. No. 3876-145, 5% RTU]		
		[MAI] 0.05-8.25 lb/ 1,000 bbl water (5% RTU)	Water treatment (0.15 to 25 ppm active ingredient). Slug or intermittent method. When the system is noticeably fouled, or to maintain control of the system, apply 0.5 to 8.25 pounds (1.5 to 25 ppm) intermittently for 4 to 8 hours per day, and from 1 to 4 times per week or as needed depending on the severity of contamination. Continuous method. When the system is noticeably fouled, apply 0.5 to 8.25 pounds (1.5 to 25 ppm) continuously until the desired degree of control is achieved.

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	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Oil Field Water Systems (oil field water, polymer or myceliar floods, water disposal systems or other oil field water systems) (continued)		
			Subsequently, apply 0.05 to 1.5 pounds (0.15 to 4.5 ppm) continuously or as needed to maintain control. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
/65008MA	Pulp and Paper Mill Systems		Apply directly to the pulp and paper mill system at a point where the formulation will be uniformly mixed.
DBABAAA	Slime-forming bacteria	[MAI] 0.0075-0.1 lb/ST pulp or paper produced [3.7-50 ppm a.i.] (5%, 10% RTU) [MAI] 0.005-0.4 lb/ 1,000 gal additive system [0.6-48 ppm a.i.] (5%, 10% RTU)	Water treatment. Intermittent or slug method. Initial dose: When the system is noticeably fouled, apply 0.0075 to 0.1 pound per short ton. Apply 0.005 to 0.4 pound directly to the additive system. Repeat until control is achieved. Subsequent dose: when control is evident, apply 0.0075 to 0.1 pound per ton. Treat as needed to maintain control. Apply 0.005 to 0.2 pound to the additive system. Continuous method. Initial dose: When the system is noticeably fouled, apply 0.0075 to 0.1 pound per ton. Apply 0.0075 to 0.4 pound directly to the additive system. Repeat until control is achieved. Subsequent dose: Continuously feed to maintain a dosage of 0.1 to 0.03 pound per ton. Apply 0.01 to 0.15 pound to the additive system. Formulated with methylene bis-(thiocyanate); or alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
FYABDBB	Slime-forming fungi		

DODECYLGUANIDINE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65026MA	Sewage Disposal Lagoons		
PKAAAAA	Algae	0.33-0.5 oz/ 100 sq.ft of surface (33% RTU)	Water surface treatment. Dosage depends upon the population density of the algal blooms. The interval between treatments depends upon the reappearance of algal blooms and subsequent treatments should be made as spot treatments at the same dosage as the initial treatment. Dilute with water to accommodate the delivery characteristics of the pump and spray rig, and apply evenly to the surface of the lagoon.
	INDOOR		
	(Industrial Preservatives and Additives)		
/810170A	Disposal Diapers (paper)		
A34	Bacteriostat	0.06% a.i. in paper diaper (0.06% Impr)	Impregnated paper diaper.
		-- (24.74% RTU)	Additive incorporation. Dosage rate not specified on labelling.
/810080A	Oil Recovery Drilling Fluids (packer fluids and drilling muds)		Do not apply in marine or estuarine oil fields.
DBABAAA DBAEAAA	Slime-forming bacteria Sulfate-reducing bacteria	[MAI] 5.0-50.0 lb/ 1,000 bbl or 8.0-80 ppm a.i. (10% RTU)	Additive incorporation. Add directly to the packer fluid or drilling mud. The dosage rate will depend upon the severity of the contamination. Formulated with methylene bis-(thiocyanate).

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/810100A	Paper and Paper Products		
A24	Bacteriostat	0.0175-0.2% a.i. by weight of paper or paperboard (24.74% RTU)	Preservative incorporation.
		0.045% a.i. in sterilized glassine paper (0.045% Impr)	Impregnated glassine paper.
		0.02% a.i. in napkins (0.02% Impr)	Impregnated napkins.
A24 FYADQBB FYAHQBB	Bacteriostat Fungi Yeasts	up to 0.4% a.i. by weight of paper or paperboard or up to 0.8% a.i. by weight of paper or paperboard (33% RTU)	Preservative incorporation. Formulation may be added to the pulp stock in the beater or applied to the formed sheet by size press or rollcoater, or as a uniform spray. Food packaging. Apply in accordance with 21 CFR, Section 176.170: For use only in paper and paperboard to be in contact with aqueous and fatty nonalcoholic foods having a pH above 5 at a level not to exceed 0.4 percent active ingredient by weight of the paper or paperboard; or, for use in the outer ply of multiwall paper bags for contact with dry foods (dry solids with the surface containing no free fat or oil) at a level not to exceed 0.8 percent active ingredient by weight of the paper. Industrial or agricultural paper and paperboard products. Add up to 0.8 percent active ingredient by weight of paper or paperboard when paper or paperboard product is to be subjected to excessive leaching as by rainfall or contact with ground water.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Paper and Paper Products (continued)		
FYA5QBB	Mold inhibition	[MAI] 0.5-2.0 lb/ST of dry fiber produced or 20-100 ppm a.i. in the sizing solution (10% RTU)	Preservative incorporation. For use in paper and paperboard grades for construction, industrial, and nonfood uses. Apply 0.5 to 2.0 pounds to the hydropulper or dump chest, or 20 to 100 ppm at the size press or water box. Formulated with methylene bis-(thiocyanate).
/810160A /810010A /810020A	Preservation of Pulp and Paper Mill Processing Chemicals, Adhesives, and Coatings		
A24 FYADQBB	Bacteriostat Fungi	[MAI] 10-100 ppm a.i. (5%, 10% RTU)	Preservative incorporation. Add directly to the material to be preserved prior to manufacturing into the finished product, i.e., pulp, broke, polymers, defoamers, alum, emulsions, adhesives, paper mill coatings, pigment slurries, and paper products. The dosage rate will depend upon the material to be preserved and the storage time. The usual addition should be 10 to 30 ppm. Under extreme conditions of spoilage, the dosage rate should be increased to 12.5 to 80 ppm. The above recommendations are based on a maximum storage time of 2 weeks. For storage time greater than 2 weeks, the maximum concentration should be increased to 50 to 100 ppm. Formulated with methylene bis-(thiocyanate); or alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).

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DODECYLGUANIDINE HYDROCHLORIDE

Listing of Registered Pesticide Products by Formulation

&233.0002 33% (2.64 lb/gal) formulation intermediate
dodecylguanidine hydrochloride (044303)
049854-00012 049854-00017

&000.0210 0.02% impregnated materials
dodecylguanidine hydrochloride (044303)
007973-00001

&000.0410 0.045% impregnated materials
dodecylguanidine hydrochloride (044303)
008683-00001

&000.0610 0.06% impregnated materials
dodecylguanidine hydrochloride (044303)
002914-00026

&205.0016 5% liquid-ready to use
dodecylguanidine hydrochloride (044303) plus alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16) (069105)
003876-00145 045017-00035

&205.2516 5.25% liquid-ready to use
dodecylguanidine hydrochloride (044303)
010445-00008

&210.0016 10% liquid-ready to use
dodecylguanidine hydrochloride (044303) plus methylene bis(thiocyanate) (068102)
003876-00121 034571-00013 045017-00028 048525-00002

dodecylguanidine hydrochloride (044303), bis(trichloromethyl) sulfone (035601) plus alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16) (069105)
003876-00052

&210.7816 10.78% liquid-ready to use
dodecylguanidine hydrochloride (044303) plus bis (tributyltin) oxide (083001)
010445-00006

&212.2516 12.25% liquid-ready to use
dodecylguanidine hydrochloride (044303)
010445-00003

&220.0016 20% (1.62 lb/gal) liquid-ready to use
dodecylguanidine hydrochloride (044303)
009640-00034

DODECYLGUANIDINE HYDROCHLORIDE

Listing of Registered Pesticide Products by Formulation (continued)

&224.7416 24.74% liquid-ready to use
dodecylguanidine hydrochloride (044303)
010445-00042

&233.0016 33% (2.64 lb/gal) liquid-ready to use
dodecylguanidine hydrochloride (044303)
049854-00010 049854-00011 049854-00016 049854-00018

EPA Compendium of Acceptable Uses

DODECYLGUANIDINE HYDROCHLORIDE

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
069105	alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16)	--
083001	bis(tributyltin) oxide	--
035601	bis(trichloromethyl) sulfone	--
068102	methylene bis(thiocyanate)	--

-- Use Common Name

EPA Compendium of Acceptable Uses

DODECYLGUANIDINE TEREPHTHALATE

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INDOOR 1

(Commercial and Industrial Uses) 1

Textiles (industrial, nonclothing textiles) 1

c044302

DODECYLGUANIDINE TEREPHTHALATE

TYPE PESTICIDE: Fungicide, Antimicrobial

FORMULATIONS: EC (0.8 lb/gal or 10%)

GENERAL WARNINGS AND LIMITATIONS: Wear goggles or face shield and chemical resistant gloves when handling. Refer to Registration Guidance Package regarding decontamination.
Product may be combined with fluorocarbons and will withstand standard textile curing temperatures.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Commercial and Industrial Uses)		
/810150A	Textiles (industrial, nonclothing textiles)		Following incorporation, the fabric may be dried on cans or on a frame.
A24	Bacteriostat	0.2-0.5% a.i. based on finished weight of fabric (0.8 lb/gal or 10% EC)	Preservative incorporation. Apply diluted with water to fabrics using conventional padding equipment. Incorporate into fabric at 0.4 to 0.5 percent active ingredient where exposure to weather or severe leaching is a factor or as low as 0.2 to 0.25 percent active ingredient for textiles to be used under indoor conditions.
FYADQBB	Fungi		

EPA Compendium of Acceptable Uses

DODECYLGUANIDINE TEREPHTHALATE

Listing of Registered Pesticide Products by Formulation

&210.0014 10% (0.8 lb/gal) emulsifiable concentrate
dodecylguanidine terephthalate (044302)
002829-00088

EPA Compendium of Acceptable Uses

DODECYLGUANIDINE HYDROCHLORIDE

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(Aquatic Sites) 2

INDOOR

(Industrial Preservatives and Additives) 10

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Brewery Pasteurizer Water 3
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Commercial and Industrial Water Cooling Systems 4
Disposal Diapers 10
Oil Field Water Systems 8
Oil Recovery Drillng Fluids 10
Paper and Paper Products 11
Preservation of Pulp and Paper Mill Processing Chemicals, Adhesives, and Coatings 12
Pulp and Paper Mill Systems 9
Sewage Disposal Lagoons 10

DODECYLGUANIDINE HYDROCHLORIDE

TYPE PESTICIDE: Fungicide, Antimicrobial, Algaecide, Molluscicide

FORMULATIONS:

FI (2.64 lb/gal or 33%)

Impr (0.02%, 0.045%, 0.06%)

RTU (5%, 5.25%, 10%, 10.78%, 12.25%, 20%, 24.74%, 2.64 lb/gal or 33%)

GENERAL WARNINGS AND LIMITATIONS: Wear goggles or face shield and chemical resistant gloves when handling. Refer to Registration Guidance Package regarding decontamination.

Observe all warnings and limitations for other active ingredients on multiple active ingredient labels.

Dosage rates are given in active ingredient. The dosage rate will depend upon the severity of contamination, the type of system, and the method of application.

Definition of Terms:

MAI - multiple active ingredient(s)

DODECYLGUANIDINE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	AQUATIC NONFOOD		
	(Aquatic Sites)		
/54018MA	Air Washer Water Systems		For use only in industrial air washer systems that maintain effective mist eliminating components. Badly fouled systems must be clean before treatment is begun.
DBABAAA FYAFQBB	Slime-forming bacteria Slime-forming fungi	[MAI] 0.01-0.1 lb/ 1,000 gal system water (10% RTU)	Water treatment (1.2 to 12 ppm active ingredient). Slug or intermittent method. Initial dose: When the system is noticeably fouled, apply 0.02 to 0.1 pound (2.4 to 12 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.01 to 0.075 pound (1.2 to 9.0 ppm) every 3 days or as needed to maintain control. Continuous method. Initial dose: When the system is noticeably fouled, apply 0.02 to 0.1 pound (2.4 to 12 ppm). Subsequent dose: Maintain initial rate by continuously feeding 0.01 to 0.075 pound (1.2 to 9.0 ppm) per day. Formulated with methylene bis-(thiocyanate).

EPA Compendium of Acceptable Uses

DODECYLGUANIDINE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/65005MA	Brewery Pasteurizer Water		Badly fouled systems must be cleaned before treatment is begun.
DBABAAA	Slime-forming bacteria	[MAI] 0.0025-0.1 lb/1,000 gal system water (5%, 10% RTU)	Water treatment (0.9 to 12 ppm active ingredient). Slug or intermittent method. Initial dose: When the system is noticeably fouled, apply 0.015 to 0.1 pound (1.8 to 12 ppm). Repeat until control is achieved. Subsequent dose: When control is evident, apply 0.0075 to 0.075 pound (0.9 to 9.0 ppm) every 3 days or as needed to maintain control. Continuous method. Initial dose: When the system is noticeably fouled, apply 0.015 to 0.11 pound (1.8 to 12 ppm). Subsequent dose: Continuously feed to maintain a dosage of 0.0075 to 0.075 pound (0.9 to 9.0 ppm) for the 10 percent formulation, or 0.0025 to 0.025 pound (0.3 to 3.0 ppm) for the 5 percent formulation. Formulated with methylene bis-(thiocyanate); or alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
FYABQBB	Slime-forming fungi		

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Dodine Standard

MRID	CITATION
00034562	American Cyanamid Company (1958) Cyprex, Dodecylguanidine acetate Residues from Pears. (Unpublished study received Mar 17, 1968 under 241-51; CDL:001692-E)
00035127	American Cyanamid Company (1958) Dodecylguanidine acetate Residues from Apples. (Unpublished study received Nov 25, 1959 under 241-51; CDL:001688-D)
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00058170	Curry, A.N. 1962. Translocation and metabolism of dodecylguanidine acetate (Dodine) fungicide in apple trees, using C-14 radiotagged Dodine. Journal of Agricultural and Food Chemistry 10(1):13-17. (Also in unpublished submission received Nov. 28, 1977 under 1730-43; submitted by American Cyanamid Co.; Consumer Products Research Div.; CDL:232344-E).
00070339	West, B.; Vidone, L.B.; O'Grady, J.J.; et al. (1958) Dodecylguanidine Acetate (DDGA): I. Acute and Subacute Toxicity--CL 7521: Report No. 58-21. (Unpublished study received Jun 27, 1969 under unknown admin. no.; prepared in cooperation with Rutgers Univ., submitted by American Cyanamid Co., Princeton, N.J.: CDL:109804-D)
00082517	O'Grady, J.J.; Winter, G.D.; Vidone, L.B.; et al. (1959) Dodecylguanidine Acetate: Two-year Feeding to Rats: Report No. 59-1. Final rept. (Unpublished study received Feb 25, 1959 under PP0211; submitted by American Cyanamid Co., New York, N.Y.; CDL: 090238-F)
00089415	American Cyanamid Company (1958) Dodecylguanidine Acetate Residues from Apples. (Unpublished study received Oct 17, 1958 under PP0211; CDL:090237-A)
00089417	American Cyanamid Company (1958) Dodecylguanidine Acetate Residues from Sour Cherries: Summary. (Compilation; unpublished study received Oct 17, 1958 under PP0211; CDL:090237-D)
00089881	American Cyanamid Company (1960) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: Cyprex 65-W. Includes method D 20 e dated Jul 2, 1958. (Compilation; unpublished study received Aug 7, 1960 under PP0324; CDL:-090352-A)
00090258	American Cyanamid Company (1964) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: Cyprex. (Compilation; unpublished study received May 5, 1964 under PP0416; CDL:090450-B)

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REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Dodine Standard

MRID	CITATION
00093588	Orloski, E.J.; Caruso, M. (1965) Cyprex Dodine Residues in Peaches: Report No. C-101. (Unpublished study received Jan 26, 1967 under 7F0577; submitted by American Cyanamid Co., Princeton, N.J.; CDL:090739-B)
00094615	Larsen, D.J. (1979) Spinach Foliar Fungicide Study. Includes method dated Apr 17, 1978. (Unpublished study, including letter dated Sep 25, 1979 from R.W. Vetro to C.F. Niven, Jr., received Feb 9, 1982 under 4E1474; submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:070669-H)
00096154	Terriere, L.C.; Kiigemagi, U. (1960) Cyprex Residues on Apples. (Unpublished study received Feb 24, 1961 under 241-12; prepared by Oregon State Univ., Agricultural Experiment Station, Dept. of Agricultural Chemistry, submitted by American Cyanamid Co., Princeton, N.J.; CDL:026957-C)
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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Dodine Standard

MRID	CITATION
00101393	American Cyanamid Co. (1958) Results of Tests on the Amounts of Residues of Cyprex Dodine Remaining on Apples. (Compilation; unpublished study received Feb 8, 1960 under unknown admin. no.; CDL:125134-B)
00101397	Howard, D.; Johnston, C. (1971) Cytox 2160: Safety Evaluation by Single Oral Administration to Bobwhite Quail. (Unpublished study received Oct 19, 1971 under 1730-22; prepared by Woodard Research Corp., submitted by American Cyanamid Co., Consumer Products Research Div., Wayne, NJ; CDL:130888-A)
00101398	Macek, K.; Sleight, B.; Shaffer, C. (1971) The Acute Toxicity of Cytox 2160 (ST 45093) to Bluegill (Lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). (Unpublished study received May 10, 1971 under 1730-22; prepared in cooperation with Bionomics, Inc., submitted by American Cyanamid Co., Consumer Products Research Div., Wayne, NJ; CDL:131387-A)
00101403	American Cyanamid Co. (19??) Cyprex Formulations: Chemical Study. (Compilation; unpublished study received Jun 28, 1978 under 241-51; CDL:234201-A)
00106142	Gabriel, K. (1972) Subacute Toxicity to Avian Species--Dietary LC50--8 Day Protocol. (Unpublished study received Jan 15, 1973 under unknown admin. no.; prepared by Biosearch, Inc., submitted by Betz Laboratories, Inc., Trevose, PA; CDL:132186-A)
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00143591	American Cyanamid Co. (1983) [Product Chemistry Data on Cyprex Technical]. Unpublished compilation. 18 p.
00157386	Kligman, A. (1977) The Evaluation of Irritating and Sensitizing Properties of Cytox 2160 by Means of the Modified Draize-Shelanski Patch Test: Protocol 3422. Unpublished study prepared by Ivy Research Labs, Inc. 7 p.

OMB Approval No. 2070-0057 (Expires 11/30/89)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2070-0057 (Expires 11/30/89)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ____________________

Applicant's Name and Address ____

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ________________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ________________________

Date ______________ Title ________________________

(April 1985)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._________________________ Date _________________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				